Barbara Calvert
Director, Medical Products
Reimbursement
Federal Government Affairs

Abbott
1399 New York Ave NW, Suite 200
Washington, DC 20005

t 202 378 2023
f 202 783 6631

Abbott

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: National Coverage Analysis (NCA) for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R)

Dear Ms. Syrek Jensen:

Abbott welcomes the opportunity to comment on the Transcatheter Aortic Valve Replacement (TAVR) national coverage analysis (NCA) opened on June 27, 2018.

Abbott is committed to helping people live their best possible life through the power of health. For more than 125 years, we've brought new products and technologies to the world -- in nutrition, diagnostics, medical devices and branded generic pharmaceuticals. We currently have a transcatheter aortic valve replacement device on the market in Europe and expect that it will be available on the US market in the future.

Abbott shares the viewpoint of the NCA requestors that TAVR therapy has achieved an established status and has demonstrated safety and effectiveness while expanding from a primarily high surgical risk population to intermediate risk patients. TAVR is no longer a new or unproven technology. The progression of TAVR therapy to a safe and commonplace procedure warrants a careful examination of the current evidence that should inform decisions about updating the current national coverage decision (NCD).

Based on currently available evidence, Abbott recommends the following:

- CMS should not institute requirements that reduce the number of TAVR sites by increasing TAVR volume thresholds; and
- SAVR and PCI volume metrics should also be de-emphasized or eliminated to determine the qualifications for a TAVR site; CMS should consider the impact on access when determining site qualifications

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TAVR volumes ≠ TAVR Outcomes

As noted by the requesters of the NCA, there is limited evidence supporting minimum volume thresholds as criteria for TAVR program initiation or continuation. Recent analysis of TVT Registry data is the only study suggesting a relationship between TAVR volume and outcomes. This analysis[1] indicates increasing site volume is associated with lower in-hospital, risk-adjusted outcomes. However, the study had significant limitations including imperfect adjustment for patient characteristics and the inability to distinguish between volume-outcomes and the "learning curve".

Analysis of more recent data, limited to recently introduced products, has shown no volume threshold-outcome relationship. This analysis has been presented by Dr. Martin Leon on behalf of the Advanced Medical Technology Association (AdvaMed) at the September 25 MEDCAC meeting on TAVR volumes. The analysis, limited to recently released devices, shows no correlation between TAVR volumes and mortality or strokes.[2] Furthermore, the TVT Registry demonstrates excellent outcomes. Over 150 low volume centers (less than 50 TAVRs annually) reported 0% in-hospital mortality in 2016.[3]

Based on this finding, we recommend that TAVR volume thresholds should not be increased, and alternative quality based metrics should be identified to replace the current volume requirements as soon as possible.

SAVR volumes relationship to TAVR outcomes

When TAVR therapy was commercially introduced, it was necessary to establish qualifications for sites to begin a TAVR program. The TAVR NCD was implemented with minimum SAVR and PCI volume requirements mirroring the requirements established by early clinical studies which considered the study site's existing structural heart experience and infrastructure. With the rapidly growing experience and understandingof TAVR procedures, it is now possible to shift to more relevant metrics.

Shifting the emphasis away from non-TAVR metrics is supported by MEDPAR data analysis showing TAVR outcomes have not been affected by either surgery or PCI volumes. This analysis, performed for AdvaMed, was also presented by Dr. Martin Leon at the MEDCAC meeting. Like the TAVR volume analysis discussed above, there was no statistically significant correlation between TAVR mortality and SAVR or PCI volumes. [4] It may also be important to consider the expected reduction in SAVR procedures as TAVR continues to gain acceptance in lower risk populations, making SAVR volumes thresholds harder to meet for some centers.

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[1] Carroll JD et al. Procedural Experience for Transcatheter Aortic Valve Replacement and Relation to Outcomes. J Am Coll Cardiol 2017; 70:29-41

[2] Leon, M. Medicare Evidence Development & Coverage Committee (MEDCAC), TAVR Program Requirement, Presentation, July 25, 2018

[3] Leon, M., Surveying the Present and Future Landscape of TAVR: A Patient-Centered Focus. TVT 2018 (The Structural Heart Disease Summit 2018) (Chicago, IL, 2018).

[4] Leon. MEDCAC presentation, July 25, 2018

Given this lack of correlation, SAVR and PCI volume metrics should be de-emphasized or eliminated to determine the qualifications for a TAVR site. However, we recognize the importance of an institution's proficiency with SAVR procedures to provide a clinically sound TAVR program. We recommend that quality metrics, such as STS ratings, might be used to evaluate SAVR proficiency.

Maintaining Medicare Beneficiary Access to TAVR

It is important to ensure that high quality TAVR procedures and outcomes are maintained into the future. As discussed above, reducing the number of sites based on volume metrics is unlikely to ensure this quality goal, and may severely limit access to TAVR procedures for some sub-populations of Medicare beneficiaries. We are concerned that geographic disparities and access for underserved populations may get worse if TAVR sites are further limited.

The MEDCAC presentation[5] by Dr. Leon, prepared for AdvaMed, identifies the following issues related to access to TAVR sites:

- Reductions based on thresholds suggested in the specialty societies' 2017 draft consensus statement[6] would drive a 39% decrease in the number of existing TAVR sites in the U.S. (50 TAVR/ 30 SAVR annual volume requirements)[7]
- SAVR-only centers in the U.S. create care-giver and referral biases resulting in disparities in optimal AS treatment;
- Increased volume threshold requirements will further limit patient access to TAVR, as an alternative, when the aging population and expanded clinical indications will demand more (not less) access to TAVR; and
- Decreased access to TAVR will result in prolonged AVR treatment wait-times and geography-based constraints that will negatively impact AS outcomes.

Availability of treatment for AS patients should include all therapy options, including TAVR, surgery, medical care and palliative care as appropriate for clinical circumstances. Patients' access to optimal care should not be limited by arbitrary volume requirements that are not associated with quality outcomes.

Shared Decision Making (SDM)

Limited access to TAVR is likely to make implementation of a robust SDM program difficult, if not impossible. SDM and its potential to incorporate patient-defined goals into treatment plans, promises to have a profound impact on the treatment of AS patients and their outcomes.

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[5] Leon. MEDCAC presentation, July 25, 2018

[6] Bavaria JE, Tommaso CL, Carroll JD, Deeb GM, Feldman TE, Gleason TG, Horlick EM, Kavinsky CJ, Kumbhani DJ, Miller DC, Seals AA, Shemin RJ, Sundt TM, Thourani VH. 2017 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Requirements for Transcatheter Aortic Valve Replacement. J Am Coll Cardiol 2017;

[7] Leon, MEDCAC presentation, July 25, 2018

The concept of SDM is impossible in an environment when all therapies are not available to all patients. Patients identify key meaningful benefits to be rapid return to normal daily activities, improved early QOL, and reduced procedure-related discomfort. Patient choice of therapy may also be impacted by factors such as geographic location of where they can receive the therapy, preference for familiar local providers, and economic barriers such as family costs associated with travel. The absence of TAVR in an AS treatment program would reduce the options available to help patients achieve their most meaningful goals, limit therapy options, and negatively impact the overall outcomes of the program.

Conclusion

There is limited evidence that TAVR volumes directly determine outcomes for TAVR sites and no evidence that SAVR and PCI volumes indicate outcomes. We believe, based on available evidence, that any changes to the NCD which limit access based on volumes will increase geographic disparities, further limit access for underserved populations, reduce the success of shared decision making programs, and reduce overall outcomes for patients with aortic stenosis.

Thank you for consideration of our comments.

Sincerely,

Barbara J. Calvert