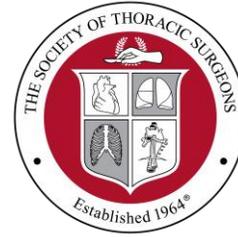




AMERICAN
COLLEGE *of*
CARDIOLOGY



July 27, 2018

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

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

Dear Ms. Syrek-Jensen:

The American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), Society for Cardiovascular Angiography and Interventions (SCAI), and Society of Thoracic Surgeons (STS) are the professional medical societies representing the physicians and health care professionals who care for aortic stenosis patients having TAVR and surgical aortic valve repair (SAVR) procedures. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' request for comment on this NCA to reconsider the national coverage determination (NCD) for TAVR.

We strongly recommend continuation of the NCD under Coverage with Evidence Development (CED) with updates based on the 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement.¹

¹ Jointly Published:

Bavaria JE, Tommaso CL, Brindis RG, et al. 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement: A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons. [Published online July 18, 2018]

The Annals of Thoracic Surgery

DOI: <https://doi.org/10.1016/j.athoracsur.2018.07.001>

[https://www.annalsthoracicsurgery.org/article/S0003-4975\(18\)30979-2/pdf](https://www.annalsthoracicsurgery.org/article/S0003-4975(18)30979-2/pdf)

Journal of the American College of Cardiology

DOI: <https://doi.org/10.1016/j.jacc.2018.07.002>

<http://www.onlinejacc.org/content/early/2018/06/20/j.jacc.2018.07.002>

Journal of Thoracic and Cardiovascular Surgery

Background

AATS, ACC, SCAI, and STS have joined together again to provide recommendations for institutions and individuals to assess their suitability for instituting and/or maintaining a high-quality TAVR program. The attached consensus document serves as the main portion of our comments and is the foundation upon which the societies recommend that CMS develop an updated TAVR NCD. As a treatment option, TAVR has become so integral to the care of patients with aortic stenosis today that the impact of an updated NCD will be profound and far-reaching even beyond those patients who may receive a transcatheter valve. Accordingly, the standards specified in the document set criteria for the development and maintenance of TAVR programs in the spirit of optimizing quality outcomes and patient safety for all patients with aortic valve disease. These requirements include:

- *Coordinated care by a multi-disciplinary team that incorporates a shared decision-making process.* The complexities of aortic stenosis patient care require a comprehensive, team-based approach to care.
- *Minimum performance on quality benchmarks.* All sites should measure outcomes. Sites with worse than expected performance for two consecutive reporting periods should enter a remediation process and conduct thorough programmatic assessments, identify gaps and opportunities for improvement, and implement corrective action plans. To enable valid performance metrics and national benchmarks, data and analytics are needed from both the STS-ACC Transcatheter Valve Therapy (TVT) Registry and the STS National Database.
- *Program Proficiency Surrogates (Volume Thresholds or External Program Monitoring).* Volume requirements are needed to maintain program effectiveness and garner sufficient sample size for quality measurement. Although important for all TAVR sites, it is especially critical that sites not meeting volume thresholds should establish rigorous monitoring and active quality assessment and improvement processes. Such programs are often facilitated by external review and recommendations.
- *Active participation in a prospective, national, audited registry.* Only through continued data collection, analysis, and feedback can outstanding clinical questions be answered under CED. Furthermore, the TVT Registry is essential for monitoring, quality and patient outcomes.

The expert consensus document provides guidance and support for a large number of centers throughout the U.S. with a focus on quality outcomes. The professional societies do not recommend that sites failing to meet all requirements should close their TAVR programs. We do, however, believe it is essential that all TAVR sites continue reporting data on TAVR procedures to a national registry. Ongoing data collection and analysis enables quality outcome measurement. Sites should review their quarterly outcome reports to assess performance in relationship to national benchmarks.

Structural Requirements

We believe that certain skills, experience, procedural volumes, and facility capabilities are required of institutions and operators in order to demonstrate the appropriate infrastructure for a successful TAVR program. These standards are explained in Section 4 of the expert consensus document and summarily displayed in Tables 4 and 5. Case volume requirements listed in the document were selected to ensure a minimum foundation of data necessary to maintain program and operator effectiveness and sufficient sample size to measure quality outcomes. Low annual volumes of SAVR or TAVR require increased scrutiny of quality because of wider statistical confidence bands and greater variability of outcomes. Sites that do not meet volume standards may still provide high-quality TAVR care. However, rigorous program monitoring (including quality assessment, root cause analysis and improvement programs) is particularly important at these sites.

Process Requirements

Best practices and standardized processes for a quality TAVR program are addressed in Section 5 of the expert consensus document. These include the incorporation of appropriate use criteria for patient selection, coordination of care and decision-making by a multi-disciplinary team, and inclusion of valvular heart disease patients and their families in a shared decision-making process. Many best practices were previously published in the *2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults with Aortic Stenosis*.²

Outcome Requirements

In Section 6, the document identifies relevant outcome measures and sets requirements for programs to demonstrate quality. These include outcome measures for both isolated SAVR and TAVR. TAVR centers must take immediate action and consider outside review to address signals of poor performance. Statistically reliable identification of low performing outliers is problematic with low volumes. This highlights the importance of even more rigorous case by case quality monitoring for these low volume programs, which may include external review. Confirmed outliers on outcome measures should undergo external review to identify causes and to suggest remediation strategies and tactics.

Registry Requirements

The Societies strongly believe that only through continuation of the CED paradigm can existing and new clinical questions be adequately answered. Submission of data on all TAVR procedures to a national registry should continue to be required. Section 7 details how data should be collected and used to assess the ongoing evolution and dissemination of TAVR technology. Data collection by a national registry facilitates programmatic assessment and quality improvement. The existing requirement to submit data to a national registry allowed improved access to TAVR for Medicare beneficiaries by facilitating the FDA's label expansion for bioprosthetic structural valve deterioration (valve-in-valve) and alternative vascular access approaches. Data collection, analysis, and feedback have enhanced the field's understanding of valve disease therapies with 37 papers published in a number of journals as of this writing, including *Health Affairs*, the *Journal of the American Medical Association* and the *Journal of the American College of Cardiology*. Perhaps more importantly, registry data will continue to answer major

² Otto, et al. J Am Coll Cardiol. 2017 Mar 14;69(10):1313-1346.

clinical questions regarding patient selection, device durability, especially with yet to be approved third generation devices, and real-world outcomes in intermediate-risk patients. In the not-too-distant future these same questions will likely need to be answered with data for low-risk patients. We strongly urge CMS to continue CED to answer these questions as indications continue to change and devices evolve in the coming years. Specific questions for consideration under future CED include:

1. What are long-term mortality outcomes and associated patient factors, especially in lower risk patients?
2. What are health status outcomes and associated patient factors at one year, especially in lower risk patients?
3. Which institutional characteristics are associated with better outcomes?
4. How do outcomes in intermediate and low-risk patients compare with pivotal trials performed for regulatory approval?
5. What are use patterns and impacts of emerging adjunctive therapies and technologies, e.g. embolic prevention devices?
6. How do institutional 30-day risk adjusted outcomes compare for TAVR and SAVR? Does good performance with one correlate with the other?
7. What patient-level risk factors for TAVR versus SAVR can better inform shared decision-making to define profiles for optimal procedural selection?
8. How should further investigation of the barriers to access that exist for underserved populations be conducted?
9. How do SAVR and PCI site volume requirements correlate to TAVR outcomes and performance?

Access to Aortic Stenosis Therapy

The societies have closely analyzed the question of whether patient access to TAVR therapy is unduly limited and found no credible scientific evidence supporting an access problem; however, continued investigation is warranted. It is encouraging that in the last two years new TAVR sites have opened in underserved regions and it is important that they remain active if they can document acceptable quality, even if they should fall below volume thresholds. The evidence demonstrates that current patient access to TAVR therapy is reasonable and that overall volume growth of TAVR in the U.S. will continue to accelerate, particularly with the expansion of indications to intermediate risk patients and potential expansion to patients at low risk for SAVR.

The United States is a large country with many regions of low population density. As a consequence, access to high quality TAVR may require additional travel time and expense for patients who live farther away from a TAVR program. Striking the right balance between maintenance of high quality outcomes and providing adequate access to care will need to be continually assessed with evidence. Some patients in regions with higher population density face obstacles for other reasons. Barriers to medical care in the United States are complex and multifactorial and access to TAVR is no different. Socioeconomic, cultural, even transit obstacles can hinder patient access to health care anywhere in the country. To that end, education of providers throughout the healthcare system must increase significantly, in a focused and structured manner, so that candidates for TAVR therapy are correctly identified and referred for specialized valvular disease care. In addition, a panel member at the July 25 MEDCAC meeting suggested the initiation of a demonstration project to support several TAVR sites in underserved geographic areas.

Tamara Syrek-Jensen, JD

July 27, 2018

Page 5

We support this recommendation and welcome the opportunity to partner with CMS as you further discuss this concept.

Thank you for considering these comments and the attached Expert Consensus Document as the NCD reconsideration is initiated. We look forward to continuing our collaboration with CMS and other stakeholders to advance the field of TAVR therapy. Please contact our respective staffs if you have any questions or concerns that we might address as you progress through the process.

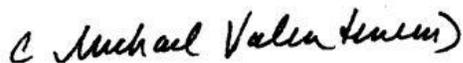
Sincerely,



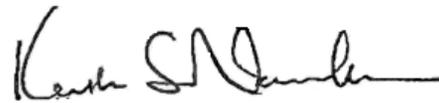
David H. Adams, M.D.
AATS President

David Cox, MD

David A. Cox, MD, MSCAI
SCAI President



C. Michael Valentine, MD, FACC
ACC President



Keith S. Naunheim, MD
STS President

Enclosure

cc: Adam Silva, AATS, Director of AATS Operations
James Vavricek, ACC Director of Medicare Payment & Coverage Policy
Francesca Dea, CAE, SCAI Executive Director
Dawn R. Gray, SCAI Director, Reimbursement & Regulatory Affairs
Courtney Yohe, STS Director of Government Relations