January 14, 2026

RE: CAG-00430R2 National Coverage Analysis for Transcatheter Aortic Valve Replacement

The American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), the Heart Failure Society of America (HFSA), Society for Cardiovascular Angiography and Interventions (SCAI), and the Society of Thoracic Surgeons (STS) are the professional medical societies representing the physicians and health care professionals who care for aortic stenosis patients who undergo transcatheter (TAVR) or surgical (SAVR) aortic valve replacement procedures for the treatment of severe aortic stenosis (AS). We appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on this National Coverage Analysis (NCA) to reconsider the national coverage determination (NCD) for TAVR.

We strongly recommend continuation of the NCD under Coverage with Evidence Development (CED), grounded in the principles outlined in the *2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement* (Bavaria et al., 2019).

Background

The Societies joined together to provide recommendations for institutions and operators to assess their suitability for instituting and/or maintaining a high-quality TAVR program. The 2018 consensus document (Bavaria et al., 2019) served as a framework for the original NCD update and continues to provide the foundational principles for program standards. Building on that foundation, the Societies now recommend that CMS update the TAVR NCD to incorporate new indications approved by the U.S. Food and Drug Administration (FDA)—such as treatment for asymptomatic AS and to anticipate future expanded indications for TAVR, including aortic regurgitation, bicuspid aortic stenosis, moderate aortic stenosis, and others. As TAVR has become integral to the care of patients with AS, the impact of an updated NCD will be profound and far-reaching, influencing not only patients who undergo TAVR but also the broader systems of care for all individuals with aortic valve disease. Accordingly, the standards specified in the document set

criteria for the initiation and maintenance of TAVR programs in the spirit of optimizing quality outcomes and safety for all patients with AS. These requirements include:

- Coordinated care by a multi-disciplinary heart team (MDHT) that incorporates a patient-centered shared decision-making process. The complexities of AS care require a comprehensive, team-based approach.
- Minimum performance on quality benchmarks. All sites should measure and report outcomes of AVR. Sites with worse than expected performance for two consecutive reporting periods should enter a remediation process and conduct a thorough programmatic assessment, identify gaps and opportunities for improvement, and implement corrective action plans. To enable valid comparison against national benchmarks, risk-adjusted data and analytics ideally can be utilized from both the STS-ACC Transcatheter Valve Therapy (TVT) Registry and the STS Adult Cardiac Surgery 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 establish rigorous monitoring and active quality assessment and improvement processes. Such activities are often facilitated by external review.
- Active participation in a prospective, national, audited registry is essential. Only through continued data collection, analysis, and feedback can clinical questions and the performance of TAVR for new indications regarding procedural outcomes be answered under CED. Furthermore, use of the audited TVT Registry—built on a single, standardized Case Report Form (CRF) with agreed upon definitions—is essential for monitoring quality and patient outcomes, as opposed to administrative or EHR-scraped data. This approach enables accurate monitoring of quality and patient outcomes. The ability to directly assess real-world outcomes is increasingly important for beneficiary access to emerging technologies.

The multi-society consensus document provides guidance and support for a large number of centers throughout the U.S., emphasizing quality outcomes. While the professional societies do not explicitly recommend that sites failing to meet all requirements end their TAVR programs, it is essential that all TAVR sites continue reporting data to a national registry. Ongoing data collection and analysis enable quality outcome measurements. Sites should review their quarterly outcome reports to assess performance against national benchmarks.

Coverage Indications

Since the first TAVR NCD, coverage has aligned with those indications approved by the U.S. FDA, enabling the policy to evolve as evidence develops. At present, the NCD still restricts coverage to symptomatic AS; therefore, the newly FDA-approved indication for asymptomatic AS is not covered outside of clinical trials. The Societies recommend CMS consider updating the coverage indication to "aortic valve disease" to enhance the longevity of the NCD should future studies garner additional indications from the FDA for TAVR procedures to address aortic regurgitation, moderate aortic stenosis, and other evolving potential indications.

Structural Requirements

The current standards and requirements have produced one of the most successful rollouts of a new therapeutic procedure in history. CMS has created a well-functioning, high-quality service model that supports the entire care team. The Societies strongly believe that continuation of the current model is essential to ensure maintenance of the highest quality and safe patient outcomes.

Available evidence supports the concept that certain skills, experience, procedural volumes, and facility capabilities are required of institutions and operators to demonstrate the appropriate infrastructure for a successful TAVR program. These standards are explained in Section 4 of the multi-society consensus document and summarily displayed in Tables 4 and 5 (Bavaria et al., 2019). Robust analyses from the TVT Registry have consistently demonstrated an inverse relationship between TAVR volume and clinical outcomes. Among 113,662 intermediate- and high-/prohibitive-risk patients treated at 555 U.S. hospitals (2015–2017), risk-adjusted 30-day mortality was inversely associated with both hospital and operator volumes (Vemulapalli et al., 2019). In a larger cohort of 384,394 patients undergoing TAVR at 453 hospitals (2013-2022), including low-risk patients, lower hospital volume was associated with higher 30-day mortality and morbidity (Kumbhani et al., 2024). Most recently, an operator-level analysis of 358,943 TAVR patients treated at 827 hospitals (2020-2023) demonstrated inverse associations between operator volume and procedural success, 30-day mortality, and morbidity (Kumbhani et al., 2026).

Together, these findings support a blended quality framework that incorporates both outcomes-based metrics and minimum volume thresholds, rather than reliance on outcomes alone. The Societies recommend revisiting the volume requirements to ensure they reflect current evidence. Any changes to volume thresholds should be contingent on mandatory reporting to a national, audited registry to enable ongoing monitoring.

Minimum volume requirements are particularly important given the well-defined learning curve for new operators and programs, which are often low-volume. In addition, low event rates for outcomes such as mortality and stroke limit the reliability of quality assessments at low-volume sites due to wide confidence intervals and greater statistical uncertainty. Recent data also demonstrate inferior process-of-care metrics among low-volume operators (for instance, longer procedure times, greater contrast use, and higher post-procedure gradients and paravalvular regurgitation)—factors likely to influence long-term outcomes, and a particularly important consideration for low-risk patients (Kumbhani et al., 2026). While some sites and operators below volume thresholds may still deliver high-quality TAVR care, rigorous program oversight (including continuous quality assessment, root cause analysis, and targeted improvement efforts) is especially critical in these settings. These volume and institutional requirements will become even more important as the indications for TAVR expand.

Available evidence supports defining minimum thresholds for hospitals and operators below which outcomes are statistically and meaningfully different. Based on available data from the TVT registry, this threshold could be defined as <37 procedures per year for hospitals (Vemulapalli et al., 2019) and <15 per year for operators (Kumbhani eta al., 2026), which is concordant with <16 per year for operators reported in 2019 (Vemulapalli et al., 2019). While there is no clear evidence-based answer for the minimum volume below which statistical uncertainty about quality becomes significant, CMS previously listed 20 per year for hospitals in the 2019 NCD to address this issue. We strongly support continuing these minimum volume requirements.

Finally, the societies recommend eliminating the PCI volume requirement, as recent evidence indicates PCI volume is not associated with TAVR outcomes (Butala et al., 2020). The original rationale for PCI volume was to ensure adequate cath lab infrastructure, which can now be assessed through other structural and process measures.

Process Requirements

Best practices and standardized processes for a quality TAVR program are addressed in Section 5 of the multi-society 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. The integral role of the multi-disciplinary heart team in joint decision making and procedures is essential to guide optimal therapy for patients with aortic valve disease, and we strongly support continuing these requirements.

Outcome Requirements

In Section 6, multi-society consensus document (Bavaria et al., 2019) 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 reviews to address signals of poor performance.

Importantly, more recent literature shows that a modeled outcome-based spoke and hub paradigm of TAVR care has the potential to improve national outcomes to a greater extent than a simulated volume threshold. While no significant reduction in estimated adverse events was noted between TAVR sites performing 50 or more versus less than 50 TAVR procedures annually, transitioning care to the best outcome site in a hospital referral area resulted in significantly fewer adverse events (Nelson et al., 2023).

Registry Requirements

For both the recently approved indication for asymptomatic AS and any future indications, it is critical to demonstrate that real-world outcomes match the safety and effectiveness reported from clinical trials. The EARLY TAVR trial (Généreux et al., 2025) randomized 901 patients with asymptomatic severe AS at 75 centers to either TAVR with a balloon-expandable valve (n=455) or clinical surveillance (n=466). TAVR was superior to clinical surveillance in reducing the composite primary end point of death, stroke, or unplanned hospitalization for cardiovascular causes. These

results supported FDA approval of TAVR for asymptomatic severe AS in this patient cohort. However, it remains essential to demonstrate that similar outcomes can be achieved in routine, real-world practice. This is necessary to not only confirm safety and effectiveness but also to ensure the procedure meets Medicare's standard of being reasonable and necessary for beneficiaries. Because randomized controlled trials occur in controlled environments in a highly-selected patient population, real-world evidence-such as data from the TVT Registry—is essential to validate that TAVR for asymptomatic AS delivers comparable results in broader patient populations.

The Societies strongly believe that continuation of the CED paradigm is essential to address existing and emerging clinical questions. Submission of data on all TAVR procedures to a national registry should remain a requirement. Section 7 in the multi-society consensus document (Bavaria et al., 2019) 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, and the current requirement has already facilitated expanded access for Medicare beneficiaries—supporting FDA label expansions for TAVR to treat bioprosthetic structural valve deterioration and alternative vascular access approaches. Moreover, registry data have advanced the field's understanding of valve disease therapies with close to 150 papers published in several high-impact journals as of this writing, including *NEJM, Lancet, JAMA, Health Affairs, Journal of the American Medical Association Cardiology, Circulation, and the Journal of the American College of Cardiology,* among others. More importantly, registry data will remain essential for addressing major clinical questions – such as optimal patient selection, long-term device durability, especially with yet to be approved devices from additional manufacturers, and real-world outcomes in asymptomatic patients. Lifetime management of asymptomatic patients, in particular, is going to be very important, as long-term data are still limited in this patient population.

As indications expand and technology evolves, these questions cannot be answered without comprehensive, real-world evidence. For this reason, we strongly urge CMS to maintain the CED framework to ensure ongoing data collection and analysis. Future CED should focus on specific questions, including:

1. What are long-term outcomes, including mortality and associated patient factors in low-risk and asymptomatic AS patients?
2. What are health status outcomes and quality of life outcomes at one year, especially among asymptomatic patients?
3. Which institutional and operator characteristics are associated with better short-and long-term outcomes?
4. How do real-world outcomes for asymptomatic patients compare with pivotal trials used for FDA approval?
5. What are the utilization patterns and clinical impacts of emerging adjunctive therapies and technologies such as aortic regurgitation and treatment of moderate aortic stenosis which have been fully enrolled in clinical trials?

6. What patient-level risk factors for TAVR versus SAVR can better inform shared decision-making to define profiles for optimal procedural selection?
7. How should the barriers to access for all cardiac services that exist for underserved populations be overcome and how would this best be implemented?
8. Do patients diagnosed with asymptomatic aortic stenosis, based on current guideline criteria, experience outcomes that confirm TAVR is reasonable and necessary compared to clinical trials?

These questions become even more relevant if infrastructure, facility, and operator standards are reduced in the future. It will be imperative to track utilization and outcomes of TAVR for new indications as it disperses to smaller facilities that would provide services at lower volumes. Additionally, future CED should ensure consistent application of guideline-based definitions for asymptomatic status and standardized echocardiographic criteria for severe AS, as these are critical for accurate data collection and interpretation.

Once the TAVR field reaches maturity and sufficient real-world evidence has been collected, sunsetting CED requirement could be considered. However, given several important indications on the horizon—including valve-in-valve procedures, treatment of aortic regurgitation, and moderate AS—continued evidence development remains critical in the near term.

Access to TAVR Therapy

It is encouraging that since the last NCD reconsideration in 2019, there has been an increase in TAVR sites. Many of these are in underserved regions. It is important that they remain active if they can document acceptable quality, even if they fall below volume thresholds. A recent analysis from the TVT Registry demonstrated that between 2017 and 2023, the number of U.S. hospitals performing TAVR increased by 49%, while the number of operators increased 1.5-fold (150%). Despite this expansion, 21% of TAVR operators in the United States currently perform ≤10 TAVRs annually—averaging less than one case per month. Further expansion could lead to additional volume dilution and redistribution (Kumbhani et al., 2026). Researchers have also found that 92.1% of those over 65 years live in a hospital referral region containing a TAVR center, and patients receiving TAVR drive a median time of 35 minutes (Marquis-Gravel et al., 2020). This study was conducted between 2015 and 2017, (prior to the last NCD consideration), and is likely even shorter today, given the increase in TAVR sites from 550 in 2017 to 860 in 2025.

We acknowledge that geographic challenges and other barriers accessing TAVR exist (David et al., 2025). The U.S. has many regions of low population density. Consequently, 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 geographically needs to be continually assessed with evidence.

Barriers to medical care in the U.S. are complex and multifactorial and access to TAVR is no different in more densely populated areas. Socioeconomic, cultural, even transportation obstacles can hinder patient access to health care anywhere in the country (Nathan et al., 2021). To that end, education of providers on the identification and treatment of aortic stenosis must increase

significantly, in a focused and structured manner, so that candidates for TAVR therapy are correctly identified and referred for specialized care. However, we do not believe that many additional TAVR sites would or should open as they are unlikely to meet adequate volume standards.

Currently, there are 860 TAVR sites reporting data to the TVT Registry, compared with 550 sites nationally during 2015-2017 when it was estimated that 10% of patients lived far from a TAVR center (Marquis-Gavel et al., 2020). Therefore, the proportion of patients without nearby access is likely smaller. Furthermore, more than half of new TAVR sites opening after 2015 were located within a 30-minute drive of an existing center (Valle et al., 2021), suggesting that lowering program standards and expanding site numbers alone is unlikely to meaningfully improve access. There are roughly 1050 cardiac surgery programs in the country. Most of the roughly 200 surgical sites that are not currently performing TAVR are either geographically close to already existing TAVR sites or lack key structural elements necessary for an optimal program. Removing facility and volume standards could compromise patient outcomes without significantly addressing access gaps.

The Societies thank CMS for the opportunity to comment on the NCA for the reconsideration of the TAVR NCD and would be pleased to engage with CMS further on this issue. Please direct any questions or concerns to Amanda Stirling, Regulatory Affairs Associate, at 202-375-6553 or astirling@acc.org.

Sincerely,

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