July 15, 2026

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RE: CAG-00430R2 Transcatheter Aortic Valve Replacement

The American College of Cardiology (ACC), the Society for Cardiovascular Angiography & Interventions (SCAI), and The Society of Thoracic Surgeons (STS) appreciate the opportunity to comment on the proposed decision memo for the National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR). The current NCD has been instrumental in establishing a robust, evidence-based framework for TAVR through national registries and multidisciplinary care, and data-driven quality oversight. As the Centers for Medicare and Medicaid Services (CMS) considers updates to this policy, we believe it is important to build upon this successful foundation while maintaining the safeguards that have supported high-quality patient care and evidence generation. We strongly support modernizing the NCD and offer the following recommendations to help ensure the policy continues to promote high-quality, evidence-based, and patient-centered care.

Specifically, we recommend that CMS:

1. **Preserve the multidisciplinary Heart Team model by explicitly requiring evaluation of eligible patients with severe aortic stenosis by both an interventional cardiologist and a cardiac surgeon and maintaining collaborative decision-making as a required component of care.**

   Proposed Decision Language:
   An initial evaluation by the Heart Team, which could be asynchronous using medical records to identify patient suitability for TAVR or other treatments.

   Recommended Revision:

The Heart Team's interventional cardiologist and cardiac surgeon must evaluate the patient to determine whether the patient is a suitable candidate for TAVR or other treatments, which could be asynchronous.

2. **Maintain a targeted CED pathway for patient populations where important evidence gaps remain**, including bicuspid aortic stenosis, valve reintervention, asymptomatic severe aortic stenosis, aortic regurgitation, and moderate aortic stenosis.

   Proposed Decision Language:
   1) cover Transcatheter Aortic Valve Replacement (TAVR) for symptomatic severe aortic valve stenosis (or aortic stenosis (AS)) without the coverage with evidence development (CED) requirement; 2) expand coverage of TAVR to asymptomatic severe AS with CED; 3) revise coverage criteria related to pre-procedural patient assessment, intraoperative requirements, and operator and hospital procedural volume requirements.

   Recommended Revision:
   The Centers for Medicare & Medicaid Services (CMS) covers: 1) Transcatheter Aortic Valve Replacement (TAVR) for symptomatic severe aortic valve stenosis (AS) without the coverage with evidence development (CED) requirement; 2) TAVR with CED for patient populations and clinical circumstances where evidence gaps remain, including asymptomatic severe AS, bicuspid aortic valve anatomy, valve-in-valve TAVR, and newly FDA-approved TAVR valves.

   CMS should also consider whether additional evidence development requirements are appropriate for newly established TAVR programs that have not previously performed TAVR procedures.

3. **Maintain mandatory participation in a national audited registry**, such as the STS/ACC TVT Registry, and clarify how registry participation may be used to satisfy CED requirements and also support quality measurement requirements. Preserve nationally standardized approaches to quality measurement, benchmarking, and continuous quality improvement through registry participation and externally benchmarked performance assessment.

   Recommended Revision:
   For TAVR procedures furnished under CED, the treating heart team and hospital must participate in a prospective, national, audited registry that: (1) consecutively enrolls patients undergoing TAVR; (2) accepts all FDA-approved devices for the covered indication; (3) collects outcomes through at least one year of follow-up; (4) complies with applicable federal regulations for human subject protections; and (5) supports nationally standardized quality measurement, benchmarking, and continuous quality improvement. CMS will consider participation in a prospective, national, audited registry sufficient to meet these CED requirements.

4. **Preserve nationally standardized approaches to quality measurement, benchmarking, and continuous quality improvement through registry participation and externally**

benchmarked performance assessment, while adopting a programmatic approach to facility and operator requirements that prioritize institutional performance, multidisciplinary infrastructure, and quality outcomes over rigid operator volume thresholds alone.

Proposed Decision Language:
Hospitals must have appropriate infrastructure that includes, "A continuous quality improvement process that assesses procedural outcomes and makes necessary programmatic adjustments to assure patient safety.

Recommended Revision:
The hospital must participate in a continuous quality improvement process that uses prospective, national, audited registry-derived outcomes data and external benchmarking to assess procedural outcomes and make necessary programmatic adjustments to assure patient safety.

Our recommendations outlined focus on targeted clarifications to the proposed decision that will help ensure consistent implementation, preserve nationally standardized approaches to quality assessment and evidence generation, and maintain the multidisciplinary care model that has contributed to the success of TAVR in the Medicare population. The subsequent sections provide additional detail regarding these recommendations and the specific policy modifications needed to support high-quality, evidence-based care for Medicare beneficiaries.

Preserve a Targeted, Forward-Looking CED Pathway

The Societies agree that it is appropriate to sunset the existing CED framework designed to evaluate TAVR in high-risk patients with symptomatic severe aortic stenosis (AS) within a framework defined by hospital and operator volume requirements and programmatic quality standards. That framework has successfully achieved its intended purpose by generating substantial clinical trial and real-world evidence demonstrating the safety and effectiveness of TAVR in the Medicare population; and thereby supporting CMS's determination that TAVR is reasonable and necessary for this population.

As TAVR expands into new and more complex patient populations, we support CMS's continued use of targeted CED and strongly recommend that CMS establish a clear process for incorporating future FDA-approved indications and emerging clinical evidence into the coverage framework. We support maintaining a targeted CED pathway for newly approved patient populations and other clinical circumstances where important evidence gaps remain, particularly where TAVR use continues to evolve beyond the populations studied in the original evidence base. This approach reflects the current evidence base, aligns with clinical consensus, and supports the Administration's goal of ensuring timely beneficiary access to innovative, FDA-approved technologies while maintaining appropriate safeguards for quality and safety.

Consistent with prior multisociety recommendations, CED should apply to the following populations:

- **Patients with symptomatic severe bicuspid AS**
  Use in bicuspid valve patients is expanding rapidly despite limited prospective evidence. Due to important anatomical differences, including calcification patterns and valve morphology, procedural risk, and valve durability, long-term outcomes may differ (Halim et al., Circulation 2020; Mehaffey JH et al., Ann Thorac Surg. 2025). Because bicuspid anatomy was excluded from the pivotal TAVR trials, continued prospective evidence generation remains particularly important as use expands in this population.

- **Patients requiring prosthetic aortic valve reintervention**
  Long-term registry data are needed to better understand patterns of repeat intervention, valve durability, and patient outcomes following prior surgical or transcatheter valve replacement (Makkar et Lancet. 2023; Bowdish et al., Ann Thorac Surg. 2024)

- **Patients with asymptomatic severe AS**
  While recent trials support expanded use in select patients, routine treatment of asymptomatic individuals remains evolving. CED enables systematic tracking of outcomes, including complications such as thrombosis, infection, and device-related failure (Lindman et al., J Am Coll Cardiol Img. 2020).

- **Patients with aortic regurgitation (AR) requiring treatment by the Heart Team**
  We strongly recommend including AR under CED. Historically, TAVR trials have focused on calcified aortic stenosis, and prospective evidence in AR remains limited. With the recent FDA approval of dedicated TAVR technologies for AR, including the JenaValve system, structured real-world evidence generation is essential to ensure appropriate adoption and patient safety (Makkar et al., Lancet 2025). CMS should also clarify that the final NCD does not exclude TAVR for AR and should avoid language that could be interpreted as limiting coverage pathways for conditions that fall outside the scope of the NCD.

In the absence of clear national coverage parameters under CED, newly approved indications, such as, AR, and potential future indications currently under investigation, such as moderate AS could result in inconsistent policies across Medicare contractors, geographic variability in access, and increased administrative burden for providers and health systems. Such fragmentation undermines both equitable access and systematic evidence generation. We therefore recommend that CMS explicitly include a prospective pathway for incorporating future FDA-approved indications and clinically evolving patient populations into the CED framework to ensure continued evidence generation, appropriate monitoring of outcomes, and alignment of coverage with the current level of evidence. A prospective, flexible CED framework is a more durable and efficient policy approach than repeatedly reopening the NCD as new technologies and indications are approved. By establishing a mechanism to align coverage with evolving FDA indications and evidence development, CMS can allow the NCD to adapt over time while maintaining national consistency. Such an approach would enable timely beneficiary access to newly approved therapies, support

nationally consistent evidence development, and reduce administrative burden on CMS and stakeholders.

As additional evidence-based guidance is expected in the forthcoming 2026 ACC/AHA Valvular Heart Disease Guidelines and recent updates in international guidelines (Praz et al., Eur Heart J, 2025), we encourage CMS to ensure that the final NCD maintains sufficient flexibility to incorporate evolving clinical evidence and consensus recommendations.

Heart Team: Clarification and Safeguards Needed

The proposed language would benefit from additional clarification regarding the respective roles of the interventional cardiologist and a cardiac surgeon in the Heart Team evaluation process.
CMS proposes:

- An initial evaluation that may be conducted asynchronously using medical records
- An independent, in-person evaluation performed by a TAVR operator

As written, this may be interpreted to allow:

- Initial review by a non-physician or mid-level provider, and
- Independent evaluation performed solely by an interventional cardiologist or cardiac surgeon

We recommend that CMS clarify that both an interventional cardiologist and a cardiac surgeon must participate in the Heart Team evaluation and treatment recommendation of eligible patients with severe aortic stenosis. This clarification preserves CMS's requirement for an in-person evaluation while providing flexibility for either an interventional cardiologist or cardiac surgeon to perform the initial evaluation. The second physician evaluation may occur separately through an appropriate mechanism, such as telehealth, provided both physicians participate in the Heart Team assessment and treatment recommendation. Additionally, CMS should reinforce the Heart Team as a required component of care and clarify that the treatment recommendation must reflect collaborative physician-led decision making rather than review by a single specialty or delegation to nonphysician personnel. The Heart Team model, which requires collaborative evaluation by both interventional cardiologists and cardiac surgeons, has been central to appropriate patient selection and optimal outcomes. This collaborative approach is particularly important in patients with more complex anatomy or procedural characteristics where clinical judgment and procedural planning are most challenging.

We are also concerned that the proposed NCD weakens expectations regarding multidisciplinary Heart Team composition. The proposed language states that the Heart Team "may include nurses, advanced practice clinicians, and administrators." This permissive language creates ambiguity regarding the personnel necessary to support patient evaluation, care coordination, registry participation, quality monitoring, and longitudinal follow up. We recommend that CMS revise this language to state that the Heart Team must include nurses, advanced practice clinicians, and administrators.

Coordinators and navigators play an essential role in managing the longitudinal patient journey, coordinating multidisciplinary care, supporting documentation and registry activities, and facilitating quality oversight (Otto et al., J Am Coll Cardiol., 2017; Nishimura et al., J Am Coll Cardiol., 2019; Otto et al., J Am Coll Cardiol., 2021). CMS has recognized the importance of dedicated care coordination personnel in other complex cardiovascular programs. For example, the recently finalized National Coverage Determination for Renal Denervation requires facilities to maintain a multidisciplinary hypertension program that includes a hypertension navigator. Additionally, CMS has consistently used mandatory language in other structural heart NCDs, which specify that the Heart Team must include defined multidisciplinary specialists rather than leaving participation optional. Consistent with the current TAVR and other structural heart coverage frameworks, specifying the essential members of the Heart Team helps ensure the personnel necessary to support patient care, policy implementation, registry participation, and quality oversight are maintained while allowing flexibility in how individual programs deploy these roles.

Finally, while the Societies recognize that procedural approaches may continue to evolve over time, we do not believe the final policy should create barriers to collaborative care models. Accordingly, CMS should clarify that the participation of two qualified operators does not require additional justification for coverage when a collaborative procedural approach is deemed appropriate by the Heart Team.

Facility and Operator Volume Requirements

We appreciate CMS's effort to incorporate contemporary evidence regarding operator experience into the proposed TAVR requirements. Recent analyses from the STS/ACC TVT Registry demonstrate a persistent association between lower operator procedural volumes and adverse short-term outcomes following TAVR. In a contemporary analysis of more than 350,000 TAVR procedures performed between 2020 and 2023, operators performing fewer than 15 TAVR procedures annually experienced modestly higher rates of 30-day mortality, procedural complications, and composite adverse outcomes compared with operators performing more than 37 procedures annually (Kumbhani et al., JAMA Cardiology, 2026) At the same time, the available evidence demonstrates a continuous relationship between procedural volume and outcomes rather than a clear inflection point that identifies a single evidence-based threshold for competency. The observed differences were modest, with numbers needed to harm ranging from 143 to 250, and the analyses do not establish a definitive volume threshold below which operators can no longer safely perform TAVR. Rather, they reinforce that operator experience should be considered as one component of a broader quality framework (Kumbhani et al., JAMA Cardiology, 2026).

A more recent analysis from the STS/ACC TVT Registry further suggests that procedural volume should be evaluated within the context of broader programmatic quality and institutional performance. These findings indicate that while operator experience remains important, longer-term outcomes are further influenced by multiple factors beyond individual procedural counts alone,

including multidisciplinary team performance, institutional infrastructure, care coordination, and quality oversight (Kumbhani et al., J Am Coll Cardiol., in press, 2026).

CMS appropriately recognizes that procedural experience remains an important component of quality. However, the proposed threshold of 15 TAVR procedures annually may not fully reflect the complexity of the available data. Contemporary TVT Registry analyses found that approximately one-third of current TAVR operators performed fewer than 15 procedures annually, the threshold proposed by CMS (Kumbhani et al., JAMA Cardiology, 2026). As a result, the proposed requirement could have meaningful implications for workforce capacity and beneficiary access, particularly in regions served by otherwise well-established TAVR programs. The Societies support revisiting procedural volume thresholds with greater emphasis on outcome-based quality measures and registry performance rather than strict procedural minimums. However, recent evidence continues to demonstrate worse outcomes among lower volume programs and operators. Accordingly, we recommend that CMS adopt a balanced framework that:

- Recognizes operator experience as an important component of quality.
- Emphasizes program-level performance supported through national registry participation and externally benchmarked outcomes assessment.
- Considers hospital experience, institutional infrastructure, multidisciplinary care, and quality oversight alongside individual procedural volume.
- Prioritizes quality outcomes and programmatic performance when evaluating TAVR programs.

Such an approach would better align with the available evidence, preserve beneficiary access to TAVR services, and maintain the quality framework that has supported the safe and successful expansion of TAVR in the Medicare population.

Registry Participation with CED

Under the current proposal, while certain indications remain contingent upon participation in CMS-approved CED studies, it is unclear how these requirements will be operationalized in practice. In particular, there is ambiguity regarding the role of national registries and how institutions are expected to meet CED requirements while ensuring consistent participation in standardized data collection.

Under prior NCDs, the STS/ACC TVT Registry functioned as a CMS-recognized CED pathway, supported by a formal study protocol, ClinicalTrials.gov registration, and explicit CMS approval. This model ensured consistent, nationwide participation in standardized data collection and was central to successful evidence development and quality monitoring for TAVR. The success of this model argues for continuity wherever feasible as CMS updates the TAVR coverage framework. The registry-based approach is familiar to facilities, clinicians, and patients, has established processes for

data collection, quality oversight, and evidence generation, and has produced a substantial body of clinical and real-world evidence that has informed regulatory, clinical, and coverage decision-making. Significant changes to the operational structure of evidence development without clear implementation guidance may create confusion and variability among facilities and clinicians, potentially disrupting ongoing evidence generation efforts. While flexibility may be appropriate in certain circumstances, ambiguity regarding participation requirements, data collection expectations, or acceptable evidence development pathways can increase administrative burden on facilities by requiring local interpretation and development of operational processes that were previously standardized nationally. Accordingly, CMS should seek to build upon the existing registry-based infrastructure wherever possible while modernizing CED requirements to address evolving indications and evidence needs. Clear expectations regarding registry participation, data collection, and evidence development pathways will be essential to achieving this goal.

In the absence of clear expectations under the proposed framework, there is a risk that:

- Participation in national registry infrastructure may be interpreted as optional
- Institutions may pursue fragmented or study-specific approaches to meeting CED requirements
- CMS may not receive sufficiently accurate and comprehensive effectiveness and safety data to make fully informed decisions
- Nationally standardized evidence generation and longitudinal outcomes assessment may be significantly weakened

We also have concerns regarding how the proposed framework may function for new or expanding TAVR programs, particularly in the absence of uniformly applied CED expectations. The success of TAVR to date has been directly tied to the standards established in the NCD, including multidisciplinary care, institutional readiness, participation in structured national data collection, and ongoing quality oversight. Under the current proposal, variability in implementation may emerge. For example, a program could focus primarily on patients outside of CED-designated indications and thereby avoid participation in certain evidence development activities. This would result in incomplete national data collection, fragmented quality monitoring and uneven evidence generation across institutions, ultimately limiting the ability to consistently assess outcomes as TAVR continues to expand into new patient populations and care settings.

These concerns are further compounded by updated methodological requirements, such as the inclusion of an active contemporaneous comparator. As currently written, it is unclear how this requirement can be operationalized without access to:

- Comprehensive claims datasets or external real-world data sources
- Infrastructure beyond existing national registries

While registry-based studies can address many important clinical questions, the TVT Registry alone may not be sufficient to support all aspects of the proposed comparator framework. Without clear guidance, this requirement may create practical barriers to participation in CED and introduce additional variability in how evidence is generated across institutions.

At the same time, the success of the TVT Registry demonstrates the value of a standardized, registry-based approach to evidence development. Developed in collaboration with CMS, the TVT Registry has served as the foundation for post-market surveillance, outcomes assessment, and regulatory decision-making. Over the past decade, this model has enabled the safe and evidence-based expansion of TAVR across multiple patient populations.

Participation in a national, audited registry remains essential because it provides:

- Real-world clinical insight through detailed, procedure-specific data reflecting routine practice
- Standardization and data quality through uniform definitions, structured data collection, and rigorous auditing
- Comprehensive national benchmarking across institutions and patient populations

Movement away from this model risks fragmenting data collection, reducing transparency, and limiting CMS's ability to evaluate outcomes as TAVR expands into new indications and care settings.

Accordingly, we recommend that CMS:

- Maintain mandatory participation in a national, audited registry, such as the STS/ACC TVT Registry
- Clarify how registry-based approaches may be used to fulfill CED requirements, including whether registries may be approved as CMS-recognized CED pathways
- Provide clear guidance on how requirements such as active contemporaneous comparators can be operationalized within existing infrastructure, including through hybrid models or linked data sources
- Ensure that any CED framework maintains expectations for standardized, nationally comparable data collection across all participating institutions

Preserving and clarifying the role of registry-based CED will be essential to maintaining the programmatic quality framework that has supported TAVR outcomes to date.

<u>Continuous Quality Improvement and Safeguarding Programmatic Quality</u>

The proposed requirement for a "continuous quality improvement process" is an important component of the NCD. However, as currently written, it is insufficiently defined, with unclear

expectations for implementation and accountability. Specifically, the proposal states that facilities must maintain:

"A continuous quality improvement process that assesses procedural outcomes and makes necessary programmatic adjustments to assure patient safety."

In addition, the proposal references the use of quality measures and externally developed frameworks (e.g., those endorsed by a clinical measurement consensus-based entity [CBE] or aligned with nationally recognized quality measurement programs) to support quality assessment. However, it is unclear how these elements are intended to be operationalized in practice. It remains ambiguous whether this requirement is intended to represent a formal, standardized, and measurable process tied to validated quality measures, or whether it may be satisfied through routine institutional activities such as internal review conferences. In practice, all institutions could assert that they already meet this requirement through existing internal processes, such as morbidity and mortality conferences, without participating in standardized external benchmarking. Without additional clarity, this requirement could end up being inconsistently applied across institutions, difficult to measure in a meaningful way, and ultimately ineffective as a quality safeguard or in advancing optimal patient care delivery.

This issue becomes particularly important as the proposed NCD reduces or eliminates several long-standing programmatic requirements. The favorable outcomes achieved with TAVR to date were generated under a framework that included multidisciplinary Heart Team evaluation, national registry participation, institutional standards, and ongoing quality oversight. As the policy evolves away from certain structural requirements, nationally standardized quality measurement and externally benchmarked performance assessment become increasingly important mechanisms for monitoring outcomes, identifying variation in performance, and ensuring continued accountability across TAVR programs. Because the proposed policy continues to rely on nationally recognized quality frameworks, additional clarity regarding the role of externally benchmarked quality assessment programs would help ensure consistent interpretation and implementation across institutions. Current outcomes are strong in part due to structured benchmarking, registry participation, externally validated performance assessment, and the dedicated personnel responsible for coordinating these activities. Absent clear expectations, variation in care and outcomes may increase, particularly among newer or lower-volume programs.

The TAVR NCD represents a unique opportunity for CMS to advance a quality-based coverage framework, aligning with broader CMS efforts to incorporate national quality measures, transparency, and accountability into coverage policy. To achieve this, we recommend that CMS define minimum expectations for quality improvement that are objective, measurable, and linked to externally benchmarked data sources, including national registries and validated quality frameworks. We recommend CMS adopt the following approach:

Facilities must ensure continuous quality improvement by assessing procedural outcomes through established mechanisms, such as national registry reporting or other externally benchmarked data

systems aligned with national quality measurement frameworks, and making necessary programmatic adjustments to assure medical necessity and patient safety.

This approach would

- Reinforce quality improvement tied to validated measures
- Support consistent benchmarking across institutions
- Align with CMS's emphasis on national quality frameworks and transparency
- Enhance accountability for hospitals and clinicians

We further recommend that CMS:

- Define minimum, measurable expectations for quality improvement processes
- Clarify how national quality measures (e.g., measures endorsed by a clinical measurement CBE or similar frameworks) should be incorporated into program evaluation
- Require linkage of quality improvement activities to externally benchmarked data sources
- Maintain clear institutional standards and oversight mechanisms to support programmatic quality

This clarification is essential to ensure that continuous quality improvement is implemented in a consistent, measurable, and meaningful way across all TAVR programs, and sustains high-quality outcomes achieved under prior NCDs.

Conclusion

The success of TAVR in the Medicare population is the result of a carefully constructed framework grounded in multidisciplinary Heart Team decision-making, national registry participation, and rigorous, data-driven quality oversight. These elements have not only ensured patient safety but have also enabled continuous quality improvement, evidence generation, and transparency across institutions.

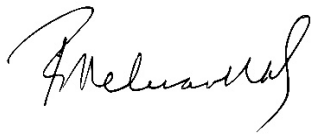
Both the clinical community and industry share a unified commitment to ensuring equitable access to care while maintaining and advancing quality in TAVR care. The proposed decision includes many important steps toward modernization of the TAVR NCD. However, there is a risk that implementation may move away from the very mechanisms that have made TAVR one of the most successful examples of coordinated, evidence-based care in modern medicine. Weakening expectations around registry participation, Heart Team engagement, and standardized quality monitoring introduces unnecessary variability.

We appreciate CMS's efforts to modernize the TAVR NCD and support many aspects of the proposed decision. Our comments are intended to clarify key operational, quality, and evidence-development provisions to ensure consistent implementation across TAVR programs while preserving the quality framework that has supported successful patient outcomes. Without additional clarification, ambiguity regarding Heart Team participation, registry use, CED

implementation, and quality oversight will create operational uncertainty, increase administrative burden, contribute to delays in care delivery, and ultimately introduce avoidable risks to patient safety. Greater clarity is essential to promote nationally consistent, high-quality care for Medicare beneficiaries.

We remain committed to working with CMS to develop a final NCD that reflects both the strength of the evidence base and the expert consensus of the clinical community. Thank you for the opportunity to comment. We respectfully urge CMS to give serious consideration to the recommendations and clarifications outlined above. Please direct any questions or follow-up to Amanda Stirling, Regulatory Affairs Associate, at 202-375-6553 or astirling@acc.org.

Sincerely,



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