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RE: CAG-00430R3 National Coverage Analysis for Transcatheter Aortic Valve Replacement (TAVR) for Aortic Regurgitation

The American College of Cardiology (ACC), the Society for Cardiovascular Angiography and Interventions (SCAI), and The Society of Thoracic Surgeons are the professional medical societies representing the physicians and health care professionals who care for patients who undergo transcatheter (TAVR) or surgical (SAVR) aortic valve replacement procedures for the treatment of aortic valve disease including aortic stenosis (AS) and aortic regurgitation (AR). We appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on the National Coverage Analysis (NCA) for TAVR in patients with AR.

The Societies strongly support timely Medicare coverage for FDA-approved TAVR therapies, including for symptomatic severe native aortic regurgitation (Grade 3+ or 4+ confirmed by echocardiography or cardiac magnetic resonance imaging) that meet guideline indications for treatment (Otto et al., 2021; Praz et al., 2025). This patient population has historically faced limited treatment options, among patients who are at high to prohibitive surgical risk. The recent FDA approval of a dedicated transcatheter therapy for native AR represents an important advancement that has the potential to expand access to life-improving and life-saving care for appropriately selected Medicare beneficiaries. At the same time, given the novelty of this indication, the limited clinical experience to date, and the need for continued evidence generation, the Societies believe coverage should be implemented through a Coverage with Evidence Development (CED) framework that both facilitates patient access and supports ongoing evaluation of clinical outcomes.

Background and Evolution of TAVR

For more than a decade, TAVR has transformed the treatment of patients with AS through a deliberate and evidence-based process involving close collaboration among clinicians, regulators,

manufacturers, and professional societies. This approach has enabled the responsible expansion of patient access while maintaining a strong commitment to evidence generation and quality improvement, providing a valuable model for the evaluation of emerging TAVR indications, including native AR.

The Societies have long supported patient access to transcatheter valve therapies when supported by evidence and delivered within a framework that promotes quality, safety, and ongoing evidence generation. Since the initial national coverage determination (NCD) (20.32), CMS has evolved coverage for TAVR to reflect an expanding evidence base, broadening coverage from patients with symptomatic severe AS at extreme surgical risk to those at high, intermediate, and low surgical risk and, most recently, to select patients with asymptomatic severe AS. Throughout these updates, CMS has maintained a consistent commitment to patient selection, Heart Team evaluation, quality oversight, and evidence generation. While specific coverage requirements have evolved over time, these core principles remain highly relevant as CMS considers coverage for new TAVR indications, including AR.

During CMS's recent reconsideration of the TAVR NCD, the ACC encouraged CMS to establish a durable and flexible coverage framework capable of accommodating evolving indications as the evidence base matures, including potential future applications for native aortic regurgitation. While CMS ultimately finalized the TAVR NCD without expanding coverage to include native AR, the Societies appreciate the agency's subsequent decision to initiate this National Coverage Analysis (NCA) to evaluate TAVR for the treatment of native AR.

As CMS considers coverage for this new indication, the ACC encourages the agency to establish a clear and predictable coverage pathway that leverages existing TAVR program infrastructure while recognizing the unique clinical considerations associated with AR. Doing so would help minimize unnecessary administrative burden, promote operational clarity for providers, and ensure timely beneficiary access to appropriate transcatheter treatment options as evidence and clinical experience continue to grow.

Aortic Regurgitation vs. Aortic Stenosis

Native AR differs from AS in several important aspects, including pathophysiology, anatomic considerations, and medical management. For instance, unlike AS, where calcified valve leaflets often provide anchoring for transcatheter valves, patients with native AR frequently lack sufficient valvular calcification and may present with annular dilation, aortic root enlargement, or associated aortopathy. Native AR may also involve more complex valve deployment, larger access requirements, increased risk of paravalvular leak, and higher rates of conduction disturbances requiring permanent pacemaker implantation. Additionally, the rate of complications such as valve embolization and need for valve-in-valve procedures is significantly higher in this setting compared with TAVR for AS. These differences can influence patient eligibility, procedural planning, device performance, and long-term outcomes, making careful patient selection and comprehensive anatomical assessment critical.

Native AR presents unique clinical, anatomical, and procedural elements that distinguish it from established AS-TAVR practice. Whereas multiple platforms are available for AS-TAVR and more than a decade of clinical experience has informed patient selection and procedural practice, AR-TAVR is a newly approved indication with a more limited evidence base and substantially less collective clinical experience. Currently, only one FDA-approved transcatheter valve system is available for the treatment of native AR for use in patients at high or prohibitive surgical risk, and its use presents distinct clinical and operational considerations, including higher observed pacemaker implantation rates. Moreover, only a small fraction of U.S. TAVR programs currently has experience with commercially available AR-TAVR systems compared with the hundreds of centers routinely performing TAVR-AS. Collectively, available evidence and real-world experience reflect approximately 1,500 native AR procedures performed to date across roughly 30 U.S. TAVR centers, including patients enrolled in the ALIGN-AR pivotal study, ARTIST, and commercial and compassionate-use experience (Vahl et al., 2024; ClinicalTrials.gov NCT06608823; Gouda et al., 2026). In contrast, nearly one million TAVR procedures have been performed for AS across 850 active U.S. TAVR centers, highlighting the substantial smaller volume of experience. Furthermore, long-term outcomes and device durability remain areas of ongoing study. Collectively, these factors underscore the importance of a thoughtful approach to coverage implementation and continued evidence development to refine patient selection, ensure patient safety, and better understand long-term outcomes.

Despite these important distinctions, several principles that have guided the successful adoption of TAVR for AS remain directly applicable to native AR. Similar to AS, patients with severe symptomatic native AR face substantial morbidity and mortality without appropriate intervention. While surgical intervention remains the mainstay of treatment and frequently requires consideration of concomitant aortic root and ascending aortic intervention in addition to valve replacement or repair, treatment options for patients at high or extreme surgical risk have been limited. The availability of an FDA-approved AR-TAVR device represents an important advancement in this underserved population. Moreover, the fundamental principles that have guided prior CMS coverage decisions remain highly relevant, including multidisciplinary Heart Team evaluations, appropriate facility infrastructure, operator experience, continued evidence development, and ongoing quality improvement.

Patient Population and Evidence Base

The patient population evaluated in ALIGN-AR (Makkar R, et al. The Lancet, 2025) provides an important reference point as CMS considers coverage parameters for this emerging indication. Key inclusion criteria included patients with predominant native AR with a trileaflet valve requiring aortic valve replacement (AVR). This was defined as a Class I or Class II indication for AVR under ACC/AHA or ESC/EACTS guideline recommendations; moderate-to-severe or severe AR (Grade 3+ or 4+) confirmed by echocardiography or cardiac magnetic resonance imaging; ascending aorta or aortic root dimension less than 5 cm; and symptomatic disease with New York Heart Association

(NYHA) Class II or greater symptoms (Otto et al., 2021; Praz et al., 2025). Patients were also required to be candidates for TAVR using the Trilogi transcatheter heart valve (THV) system (adequate iliofemoral access, favorable ascending aortic anatomy, appropriate aortic valve morphology and annular dimensions), high or extreme risk for SAVR, capable of providing informed consent, and willing to comply with longitudinal follow-up requirements. These considerations are reflected in the FDA-approved indication for the Trilogi Transcatheter Heart Valve System (FDA PMA P250024, approved March 17, 2026), which states: *"This device is indicated for the treatment of symptomatic, severe native tricuspid aortic valve regurgitation (not due to acute endocarditis, rheumatic heart disease, or acute aortic dissection) in patients who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for surgical aortic valve replacement (i.e., predicted risk of surgical mortality $\geq 8\%$ at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator)."*

The importance of careful patient selection is further reflected in international guideline recommendations. The 2025 ESC/EACTS Valvular Heart Disease Guidelines include a Class IIb recommendation supporting consideration of TAVR in selected patients with native aortic regurgitation who are ineligible for surgery (Praz F et al. 2025). Taken together, the ALIGN-AR study population, FDA-approved indication, and guideline recommendations emphasize careful patient selection through multidisciplinary Heart Team evaluation and individualized clinical assessment.

Heart Team

As CMS considers coverage for this indication, the Societies strongly emphasize the importance of a multidisciplinary Heart Team. As outlined above, patients with severe native AR frequently present with complex clinical and anatomical considerations that require individualized assessment. Unlike AS, treatment decisions may be influenced not only by valve pathology, but also by factors such as aortic root dilation, ascending aortic disease, ventricular remodeling, and other concomitant structural abnormalities. For patients not of extreme surgical risk, the current standard of care is surgery. While transcatheter treatment of native AR is currently limited to patients at high or greater surgical risk consistent with the FDA-approved indication, the field continues to evolve. As additional evidence emerges and indications potentially expand, patients with native AR, particularly those who are younger or at intermediate or lower surgical risk, may have a broader range of treatment options. Unlike AS for which valve replacement is the only available option, isolated AR may be treated with reconstructive options for the aortic valve including aortic valve repair, valve-sparing root replacement, and the Ross procedure that avoid several of the complications of prosthetic valves and are associated with better long-term clinical outcomes (Girdauskas et al., 2024; Tastet et al., 2024; El-Hamamsy et al., 2022; Mazine et al.,). Furthermore, approximately 30-40% of patients undergoing surgery for significant native AR have concomitant significant aortic pathology requiring consideration of concomitant aortic root or ascending surgery at a threshold of 4.5 cm (Anand et al., 2023; Chang et al., 2022; Praz et al., 2025). A multidisciplinary evaluation is therefore important to ensure patients understand the full range of available treatment options and engage in

informed shared decision-making regarding the risks and benefits that are individualized based on patient anatomy, clinical characteristics, and long-term considerations.

Accordingly, the Societies believe that an *in-person* evaluation by both an interventional cardiologist and a cardiac surgeon from the Heart Team must remain an essential component of patient assessment and treatment planning. This approach provides an important safeguard for appropriate patient selection and consideration of all available treatment options without relying on potentially burdensome numerical eligibility criteria that may not fully capture the complexity of individual patients. The complementary expertise of these specialists is critical to evaluating the full range of therapeutic options, including transcatheter intervention, surgical valve replacement, reconstructive options for the aortic valve, and management of associated aortic pathology.

Equally important is comprehensive multimodality imaging assessment, which plays a central role in evaluating aortic valve morphology, annular dimensions, aortic root and ascending aortic anatomy, procedural feasibility, and suitability for alternative treatment strategies. Input from these specialties helps ensure comprehensive evaluation of patient-specific anatomy, procedural considerations, and long-term treatment needs.

A collaborative Heart Team approach, including interventional cardiologists, cardiac surgeons, imaging specialists, advanced practice providers, nurses, administrators, and other clinically appropriate specialists, remains essential to determining the most appropriate treatment strategy for each patient. This framework has been a cornerstone of the successful adoption of TAVR and is particularly important for a newly approved indication where careful patient selection will be critical to achieving optimal outcomes.

Operator Requirements

It is pivotal that this NCD maintain a two-operator requirement when performing TAVR procedures for AR. Unlike calcific aortic stenosis, native AR frequently occurs in the absence of significant annular or leaflet calcification, eliminating an important mechanism for anchoring and stabilizing a transcatheter valve during deployment (Yoon et al., 2017). AR is also commonly associated with larger or dilated annuli and aortic roots, while increased stroke volume and the regurgitant “suction effect” can further complicate precise valve positioning (Franzone et al., 2016). Together, these characteristics increase the technical complexity of the procedure and the potential for valve malposition, migration, embolization, paravalvular regurgitation, or the need for conversion to surgery.

These risks are demonstrated in the available clinical evidence. The PANTHEON international registry of TAVR for pure native AR reported transcatheter valve embolization or migration in 12.4 percent of patients, with these events associated with worse short- and longer-term outcomes. Although newer dedicated devices have substantially improved procedural outcomes, the ALIGN-AR trial itself recognizes the unique challenges associated with anchoring and positioning a transcatheter valve in the noncalcified anatomy characteristic of AR (Poletti et al., 2023). Given

these procedural complexities, the evolving evidence base, and the potential need to rapidly identify and manage complications, including circumstances requiring surgical intervention, we believe the complementary expertise of two qualified operators remains an important patient safety safeguard. Maintaining a two-operator requirement helps ensure appropriate procedural planning, device deployment, real-time clinical decision-making, and management of complications as TAVR expands into this distinct and technically challenging patient population.

Coverage with Evidence Development

As experience with TAVR for native AR continues to evolve, continued evidence development will be essential to better understand long-term outcomes, identify patient populations most likely to benefit, and inform future refinements to clinical practice. The Societies believe coverage for severe symptomatic native AR is well-suited for CED. Given the limited long-term evidence currently available for TAVR in native aortic regurgitation, we believe a CED framework should be a requirement and should be structured in a manner consistent with CMS's recently finalized coverage approach for asymptomatic severe AS. While the specific clinical questions should reflect the unique characteristics and remaining evidence gaps associated with native AR, CMS should leverage existing operational infrastructure, study expectations, and data collection processes whenever feasible. Aligning study requirements, evidence development expectations, and data collection processes across newer TAVR indications would promote consistency, reduce unnecessary administrative burden, and support continued evidence generation while ensuring timely beneficiary access.

The ALIGN-AR pivotal trial (Vahl et al., 2024) demonstrated favorable safety and effectiveness outcomes and formed the basis for FDA approval. Given the absence of an approved transcatheter treatment option for this population at the time of study design and the poor prognosis associated with untreated symptomatic severe AR, a traditional randomized trial was neither practical nor ethical. Nevertheless, ALIGN-AR successfully met its prespecified safety and effectiveness endpoints, and additional evidence will continue to emerge through ongoing studies, including ARTIST (ClinicalTrials.gov NCT06608823), as well as real-world clinical experience.

The primary objective of CED should be to address remaining areas of clinical uncertainty and generate evidence that can inform future coverage decisions. Accordingly, CMS should establish clear, clinically meaningful research questions that can be prospectively evaluated and ultimately answered over time. Particular areas of interest include procedural outcomes, such as permanent pacemaker implantation, device embolization or conversion to SAVR, vascular access complications, and valve performance, as well as longer-term outcomes including durability, reintervention on the aortic valve or aorta, aortic endpoints (rupture or dissection), and survival. Defining targeted evidence gaps at the outset will help ensure that CED remains focused on generating information that is both clinically relevant and actionable for future policy considerations.

Real-World Evidence Generation and Quality Improvement

The cardiovascular community has an already established infrastructure capable of supporting both real-world evidence generation and quality assessment for TAVR in native AR. The STS/ACC Transcatheter Valve Therapy (TVT) Registry has played a central role in advancing understanding of

transcatheter valve therapies, informing clinical practice, supporting regulatory and coverage decision-making, and generating high-quality real-world evidence. Registry-derived data have informed evaluations of procedural outcomes, patient selection, operator and institutional experience, and longitudinal clinical performance, while also identifying opportunities for quality improvement across TAVR programs. The TVT Registry is particularly well-suited to support CED for native AR because it enables standardized data collection at scale, facilitates longitudinal follow-up, and provides a mechanism for evaluating outcomes in a real-world Medicare population.

While administrative claims databases and linked data sources can provide valuable information regarding longitudinal outcomes, utilization patterns, and survival, these sources cannot fully replicate the detailed clinical, procedural, imaging, and device-specific information captured within the TVT Registry. Such data sources should therefore be viewed as complementary to, rather than substitutes for, robust clinical registry participation. Particularly for a newly approved indication such as native AR, high-quality real-world evidence requires the integration of detailed clinical information with longitudinal outcomes data and remains essential to understanding patient selection, procedural performance, and device durability. As experience with this new indication grows, collection of consistent national data will be critical for addressing evidence gaps that cannot be fully answered through premarket studies alone and to informing future clinical practice and coverage decisions.

Beyond evidence development, the TVT Registry has demonstrated the value of nationally standardized quality assessment and benchmarking. Participation in a national registry enables programs to evaluate performance against standardized measures and national benchmarks, identify opportunities for improvement, and monitor outcomes over time in a manner that extends beyond traditional internal quality review activities. These capabilities help support accountability, transparency, and continuous learning across TAVR programs. The Societies are committed to ensuring that data collection remains focused, efficient, and clinically meaningful and are actively working to reduce administrative burden, including efforts to streamline registry participation and make one-year follow-up data collection optional, while preserving the Registry's essential roles in generating high-quality, real-world evidence and supporting quality improvement.

The Societies support inclusion of a quality improvement requirement for TAVR in native AR, consistent with the approach adopted in the final 2026 TAVR NCD. We appreciate CMS's continued emphasis on quality improvement and patient safety and agree that programs performing TAVR for native AR must maintain a continuous quality improvement process that assesses procedural outcomes and makes necessary programmatic adjustments to assure patient safety. We also recognize CMS's desire to provide hospitals with flexibility in how these activities are implemented rather than prescribing a single mechanism for quality oversight. While this approach reduces administrative burden and allows institutions to leverage existing quality programs, it may also result in substantial variation in how quality improvement expectations are interpreted and operationalized across programs.

As currently written, the requirement establishes an important expectation but does not specify how programs should assess performance against external standards or demonstrate compliance. Internal activities such as morbidity and mortality conferences, departmental reviews, and quality committee meetings are important components of a comprehensive quality program, but they do not necessarily provide the same degree of objective benchmarking and external performance assessment as nationally standardized quality measurement programs. Consequently, one institution may rely solely on internal review processes, while another may participate in robust benchmarking initiatives, despite both technically satisfying the same requirement.

The Societies respectfully encourage CMS to provide additional guidance regarding appropriate approaches to quality assessment and benchmarking. Rather than prescribing a single pathway, CMS could recognize participation in national registries, quality improvement programs, third-party accreditation or certification programs, state quality programs, public reporting initiatives, or other structured benchmarking processes capable of providing objective performance assessment, external benchmarking, and accountability. Such an approach would preserve institutional flexibility while promoting greater consistency, transparency, and accountability across TAVR programs.

As CMS seeks to expand access while reducing administrative burden, we believe it remains important to maintain mechanisms that support standardized performance assessment and continuous quality improvement. The success of TAVR in the U.S. has been driven not only by expanded access, but also by a longstanding commitment to evidence generation, quality oversight, and accountability. Clarifying how programs may demonstrate adherence to quality improvement expectations would help preserve these principles as experience with TAVR for native AR continues to evolve.

Conclusion

This NCD will play an important role in the implementation of TAVR for AR, particularly given the early stage of experience with this newly approved indication. The field is expected to evolve rapidly, with additional dedicated AR technologies under development and ongoing clinical studies further informing patient selection, procedural approaches, and long-term outcomes. As CMS develops a coverage framework for this indication, it will be important to maintain an approach that supports continued innovation while allowing emerging evidence to inform clinical practice. The ACC/AHA is currently developing updated valvular heart disease guidelines in conjunction with the surgical societies that will incorporate new evidence and provide recommendations regarding the appropriate use of transcatheter therapies in aortic valve disease. Together with ongoing clinical studies, real-world evidence generation, and continued quality assessment, these efforts will help refine patient selection and optimize outcomes for Medicare beneficiaries with native AR.

The Societies appreciate CMS's thoughtful consideration of this important coverage issue and its ongoing commitment to ensuring that Medicare beneficiaries have timely access to safe, effective, and innovative cardiovascular therapies. We look forward to continued collaboration as experience with TAVR for AR grows. We believe a coverage framework that promotes patient access, supports evidence development, encourages quality assessment, and preserves multidisciplinary Heart Team

decision-making will help ensure the safe, effective, and evidence-based adoption of this promising therapy for Medicare beneficiaries. 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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References

Otto CM, Nishimura RA, Bonow RO. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2021 Feb 2;77(4):e25-e197.

Praz F, Borger MA, Lanz J, et al. 2025 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J*. 2025;46(44):4635-4736.

Makkar R, Thourani V, Vahl T et al. Transcatheter aortic valve implantation with the Trilogy valve for symptomatic native aortic regurgitation (ALIGN-AR): a pivotal, multicentre, single-arm, investigational device exemption study. *Lancet*, 2025; 406, 2757-2771

Vahl TP, Thourani VH, Makkar RR, et al. Transcatheter aortic valve implantation in patients with high-risk symptomatic native aortic regurgitation (ALIGN-AR): a prospective, multicentre, single-arm study. *Lancet*. 2024;403(10435):1451-1459.

ClinicalTrials.gov. Study of Transcatheter Aortic Valve Replacement for Aortic Regurgitation. ClinicalTrials.gov Identifier: NCT06608823. Available at: <https://clinicaltrials.gov/study/NCT06608823>. Accessed September 2026.

Gouda P, Koerner J, Stebbins A, et al. Outcomes of transcatheter aortic valve replacement for primary aortic regurgitation. *Structural Heart*, 2026; Published online September 25, 2026.

U.S. Food and Drug Administration. Premarket Approval (PMA): Trilogi Transcatheter Heart Valve System (P250024). Approved March 17, 2026. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P250024>

Girdauskas E, Balaban Ü, Herrmann E, et al. Aortic valve repair results in better 1-Year survival than replacement: results from German Aortic Valve Registry. *Ann Thorac Surg*. 2024 Mar;117(3):517-525.

Tastet L, Salaun E, de Heer F, et al. Mid-term clinical and hemodynamic outcomes in patients treated for aortic regurgitation and/or ascending aorta aneurysm: the 3-year flight of the AVIATOR Registry. *Journal of the Heart Valve Society*. 2024;1(1).

El-Hamamsy I, Toyoda N, Itagaki S, et al. Propensity-Matched Comparison of the Ross Procedure and Prosthetic Aortic Valve Replacement in Adults. *J Am Coll Cardiol*. 2022 Mar 1;79(8):805-815.

Mazine A, David TE, Stoklosa K, et al. Improved Outcomes Following the Ross Procedure Compared With Bioprosthetic Aortic Valve Replacement. *J Am Coll Cardiol*. 2022 Mar 15;79(10):993-1005.

Vidhu Anand, Hanwen Hu, Alexander D Weston, et al. Machine learning-based risk stratification for mortality in patients with severe aortic regurgitation, *European Heart Journal - Digital Health*, Volume 4, Issue 3, May 2023, Pages 188–195.

Chang, H, Lo, H, Chen, W. et al. Comparison between bicuspid and tricuspid aortic regurgitation: presentation, survival, and aorta complications. *JACC*. 2022 Mar, 79 (9_Supplement) 1737.

Yoon SH, Schmidt T, Bleiziffer S, et al. Transcatheter aortic valve replacement in pure native aortic valve regurgitation. *J Am Coll Cardiol*. 2017;70(22):2752-2763.

Franzone A, Piccolo R, Siontis GCM, et al. Transcatheter aortic valve replacement for the treatment of pure native aortic valve regurgitation: a systematic review. *JACC Cardiovasc Interv*. 2016;9(22):2308-2317.

Poletti E, De Backer O, Scotti A, et al. Transcatheter aortic valve replacement for pure native aortic valve regurgitation: The PANTHEON International Project. *JACC Cardiovasc Interv*. 2023;16(16):1974-1985.