



October 9, 2026
Joanna Baldwin
Director, Coverage and Analysis Group (CAG)
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Ms. Baldwin,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Transcatheter Aortic Valve Replacement (TAVR) for Aortic Regurgitation (AR) National Coverage Analysis (NCA). Founded in 1964, STS is an 8,000 member not-for-profit organization dedicated to ensuring the best possible outcomes for therapy of the heart, lungs, and esophagus.

STS supports the multisociety comments being submitted by the American College of Cardiology (ACC), Society for Cardiovascular Angiography & Interventions (SCAI), and STS in response to this NCA. We submit these additional comments to further emphasize that surgical involvement should be required, not optional, both in the in-person evaluation of patients with isolated native AR and in the TAVR procedure for patients with AR.

These recommendations are founded solely to ensure the clarity of evaluation and the safety of TAVR for native AR as a novel and clinically distinct application to TAVR for aortic stenosis, one with substantially less clinical trial data and and real-world evidence. The difference in experience is substantial: the STS/ACC TVT Registry recorded nearly one million patients undergoing TAVR across 850 sites in the United States since 2011, while the expanded ALIGN-AR study enrolled just 700 patients with native AR across 30 U.S. centers through July 2025.^{1,2} Native AR also presents distinct anatomical and procedural challenges, including limited or absent valvular calcification, larger annular dimensions, and dilation of the aortic root, which can complicate device anchoring, positioning, and sealing and increase the risk of valve migration, embolization, and paravalvular regurgitation.^{3,4} These considerations make appropriate patient selection, multidisciplinary

¹ Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol*. 2020;76(21):2492-2516. doi:10.1016/j.jacc.2020.09.595.

² Vahl TP, Thourani VH, Makkar RR, 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(10521):2757-2771. doi:10.1016/S0140-6736(25)02215-9.

³ 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. doi:10.1016/j.jcin.2023.07.026.

⁴ 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. doi:10.1016/j.jacc.2017.10.006.

decision-making, and procedural expertise particularly important as this therapy enters broader clinical practice. Maintaining appropriate safeguards during this early period of adoption is essential to protecting patient safety and achieving optimal outcomes.

Importantly, the pivotal ALIGN-AR trial incorporated a multidisciplinary Heart Team that included both an interventional cardiologist and a cardiac surgeon to determine surgical risk and treatment eligibility, as well as to perform the procedure.⁴ STS believes Medicare coverage should reflect the framework under which the evidence supporting this indication was generated.

Accordingly, **TAVR for native AR should be performed jointly by two qualified operators—an interventional cardiologist and a cardiac surgeon.** Requiring both specialties preserves the multidisciplinary model reflected in ALIGN-AR while experience and real-world evidence continues to accumulate. The limited evidence supporting TAVR for native AR does not yet warrant the same degree of flexibility outlined in the recent TAVR NCD for symptomatic aortic stenosis and therefore data for this procedure should be captured under the provisions of Coverage for Evidence Development.

We appreciate CMS's consideration and remain committed to collaborating on policies that guarantee safe, effective, and accessible aortic valve therapies for all patients. For additional information or clarification, please contact Molly Peltzman, Director of Health Policy and Regulatory Affairs, at mpeltzman@sts.org.

Sincerely,

A handwritten signature in black ink, appearing to be 'Vinay Badhwar', with a long horizontal line extending to the right.

Vinay Badhwar, MD
STS President