May 2, 2025

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

RE: CAG-00468 Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation

Dear Ms. Syrek-Jensen:

The American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), American Society of Echocardiography (ASE), Heart Rhythm Society (HRS) and The Society of Thoracic Surgeons (STS) are the professional medical societies representing the physician and health care professionals who care for tricuspid regurgitation (TR) patients having tricuspid transcatheter edge-to-edge repair (T-TEER) and surgical tricuspid valve (TV) repair procedures. Collectively, we represent over 60,000 cardiovascular professionals. The societies are supportive of the development of a National Coverage Determination (NCD) for T-TEER and we appreciate the opportunity to comment on the proposed decision memo.

The societies are broadly supportive of the proposed decision memo for T-TEER Medicare coverage under Coverage with Evidence Development (CED). We recognize the importance of this initiative and appreciate the efforts CMS has made to ensure that patients have access to innovative treatments. We acknowledge that CMS is proposing a novel course for this NCD, which places greater responsibility on the trial sponsor for the rational dispersion of a new, breakthrough device. However, the societies remain committed to operator and institutional volume criteria, as there is strong evidence supporting this approach based on data related to mitral and tricuspid procedures (Badhwar et al., 2020; Hameed et al., 2025; Awtry et al., 2023; Sorajja et a.l, 2017).

While understanding that CMS may be charting a different path, we are committed to assisting CMS and the sponsor in navigating delivery of this new therapy. Our goal is to ensure that the implementation of T-TEER is guided by robust evidence and best practices, ultimately benefiting patients by providing timely access to care while achieving optimal outcomes.

Multidisciplinary Heart Team

Care for T-TEER patients should be overseen by a multidisciplinary heart team (MDHT) experienced in managing tricuspid regurgitation as outlined in the proposed decision memo. It has come to our attention that some hospitals are misinterpreting the MDHT requirements in the proposed decision memo as well as the final decision memo for TTVR, believing that every patient must consult with every member of the MDHT. We encourage CMS to clarify that this is not the case. It is recommended that, at a minimum, patients should be seen in consultation by an interventional cardiologist and a cardiac surgeon, with imaging reviewed by an interventional echocardiographer. Additional specialists should be included based on the patients' individual comorbidities and pathoanatomy.

Operator and Facility Requirements

The societies stand by our recommendations for operator and institutional volume requirements in order to optimize outcomes at new transcatheter TV interventional programs. As transcatheter tricuspid valve interventions (TTVI) continue to evolve, establishing facility volume requirements has become a crucial consideration in maintaining outcomes. Current registries and randomized trials show that optimal T-TEER results by TVARC criteria are achieved in only ~50% of patients and all studies consistently show residual tricuspid regurgitation is associated with higher mortality and heart failure hospitalizations. Thus the argument that even sites involved in the trial could be excluded if volume requirements were required (Vemulapalli et al., 2025) may be justified to improve efficacy of the device and outcomes. While ensuring broad access to this life-changing therapy is essential, maintaining high-quality patient outcomes is paramount and requires that centers performing these procedures accumulate sufficient experience and expertise to optimize efficacy. Striking the right balance between accessibility and procedural proficiency is fundamental to optimizing patient care, particularly for a relatively new procedure in a highly variable anatomy with known procedural complexity. From the report of the randomized controlled trial of T-TEER, the average number of devices required to achieve the limited efficacy reported, is ~2/patient with procedure time of 151.0 ± 71.7 min (Sorajja et al., 2023). Studies across various transcatheter procedures have demonstrated that hospitals with higher procedural volumes tend to have better patient outcomes. Increased experience leads to enhanced procedural efficiency, fewer complications, and improved long-term success. In TTVI—a complex and emerging field—having standardized volume thresholds can serve as a safeguard for both patients and providers.

There is strong evidence supporting the correlation between higher procedural volumes and better outcomes in TAVR (Vemulapalli et al., 2019; Mauler-Wittwer et al., 2022; Bansal et al., 2021) and mitral TEER (Chhatriwalla et al., 2019; Grayburn et al., 2024; Sorajja et al., 2017). In addition, TAVR volume also impacts outcomes for M-TEER (Awtry et al., 2023). There is growing evidence

that a volume-outcome relationship also exists for T-TEER. One study notes that setting TAVR volume criteria for defining TEER centers could help ensure the best outcomes without restricting access to care (Awtry et al., 2023). A recent report of a large tricuspid TEER registry showed that higher center experience (≥21 patients/year) resulted in higher intraprocedural and clinical success (Wild et al., 2024). The volume-outcome association has also been evaluated in a recent study comparing T-TEER with isolated tricuspid valve surgery using the Medicare fee-for-service Inpatient Claims and Master Beneficiary Summary Files (Shimoda et al, 2025). This study showed T-TEER, outcomes appear to rapidly improve up to a volume of ~20 cases but may further improve with >60 cases. This continuum of improvement mirrors the findings with M-TEER from the STS-TVT registry which showed improved outcomes (composite of MR ≤1+, no mortality and no cardiac surgery) beginning at 50 cases with continued improvement to 200 cases (Chhatriwalla et al, 2019). There may also be a relationship between surgical volume and transcatheter outcomes for specific valve interventions. Mortality and heart failure hospitalizations following mitral TEER are lower at centers with higher surgical mitral valve repair volume (Grayburn et al., 2024). Thus, the volume-outcome relationship appears to be consistent for a broad spectrum of transcatheter device therapies. In addition the total volume of transcatheter device therapies may also influence outcomes.

The societies' commitment to maintaining operator and institutional volume criteria is further supported by recent studies demonstrating the impact of procedural volume on outcomes. The bRIGHT study found no significant difference in TR outcomes between low and high-volume sites, though patients at low-volume sites had less severe disease but higher rates of new onset renal failure (Lurz et al, 2024). The PASTE registry indicated that center experience is crucial for procedural and clinical success with the PASCAL system (Wild et al, 2023). A study comparing T-TEER and isolated tricuspid valve surgery highlighted the importance of performing procedures at experienced centers for optimal outcomes, showing that higher procedural volumes are associated with decreased two-year mortality for both strategies (Shimoda et al, 2025).

Higher surgical and transcatheter volume centers are more likely to have established protocols and experienced teams, which contribute to consistent and high-quality care. These centers often have better infrastructure and support systems in place to handle the complexities of T-TEER procedures. Greater M-TEER heart team experience should translate to the T-TEER procedure with established interventionalist-imager communication and intra-procedural protocols. Surgeons and interventional cardiologists who regularly perform these procedures are more adept at managing potential complications and achieving optimal results. Regular practice and experience are crucial for maintaining and improving procedural skills. By adhering to our recommended criteria, we can ensure that T-TEER procedures are performed safely and effectively, providing the best possible care for patients with severe tricuspid regurgitation.

While ensuring access to transcatheter tricuspid valve interventions in underserved areas is critical, facilitating underperforming programs in these regions—rather than connecting patients to high-performing centers—can inadvertently become a form of healthcare inequity. High-quality, resource-intensive programs demand sophisticated infrastructure, specialized expertise, and robust

institutional support to deliver safe and effective outcomes. Lowering standards or tolerating suboptimal care in underserved areas risks reinforcing disparities rather than resolving them. Instead, the focus should remain on ensuring that every patient, regardless of geography, receives care that meets stringent safety and quality benchmarks. Strategic investments should prioritize strengthening programs that can meet these requirements rather than simply proliferating lower-performing centers under the guise of accessibility.

T-TEER should only be performed in hospitals with the appropriate infrastructure. The institution must have an active cardiac surgical program supported by at least 2 institutionally based cardiac surgeons experienced in the treatment of patients with VHD and at least one physician with interventional cardiology privileges. This aligns with the 2018 AATS/ACC/SCAI/STS Expert Consensus on Transcatheter Aortic Valve Replacement (TAVR) recommendations (Bavaria et al., 2019). Similarly, for transcatheter mitral valve interventions (Bonow et al., 2020), institutions must have at least one interventional echocardiographer; a cardiologist with level 3 training and National Board of Echocardiography certification or testamur status, or a cardiac anesthesiologist with level 2 training and advanced perioperative transesophageal echocardiography (PTeXAM) certification or testamur status.

High-quality pre- and post-procedural care facilities with staff experienced in managing open-heart surgery patients and MHDT consultations are essential. Physicians performing T-TEER must have access to a cardiac catheterization lab and an interventional/implantation suite. Operators must have access to advanced imaging, including cine fluoroscopy and 2D/3D transesophageal echocardiography (TEE) throughout the T-TEER procedure, and access to 2D/3D intracardiac echocardiography (ICE) is highly recommended. Facilities should have rapid access to a cardiac electrophysiologist with expertise in lead extraction, leadless pacemaker placement, and coronary sinus lead placement.

By their very nature, these complex procedures should only be undertaken in institutions that routinely perform surgical TV operations and participate in the STS Adult Cardiac Surgical Database with outcomes that equal or exceed those expected for their case mix relative to national benchmarks. Similarly, only institutions with interventional cardiology programs that have established programs in PCI, balloon valvuloplasty, TAVR, M-TEER, catheter closure of periprosthetic leaks, deployment of septal closure devices, and advanced mechanical circulatory support to address right ventricle dysfunction, with outcomes that equal or exceed those established nationally for similar procedures, should offer transcatheter TV intervention.

T-TEER should be performed by at least two physicians working as co-operators. An interventional echocardiographer must serve as a co-operator and provide imaging expertise during all aspects of the procedure; An interventional cardiologist or cardiac surgeon, as the other co-operator, must provide expertise in wire, catheter, and device manipulation and deployment. The interventional echocardiographer may not also provide anesthesiology care during the same procedure. At the MDHT's discretion, if appropriate, an additional physician, either an interventional cardiologist or a

cardiac surgeon, can be involved as a third operator in the procedure. We support coverage and payment that appropriately reflect the contributions of all physicians involved, especially in cases where a patient's clinical condition necessitates multiple intraoperative participants. All physicians who participate in the procedure must be board certified or equivalent in their specialty and have received device-specific training as required by the device manufacturer. All T-TEER institutions must submit complete data to the STS/ACC TVT Registry.

As the field advances, setting data-driven volume benchmarks for TTVI can help ensure that both patient safety and equitable access remain at the forefront. Standardized volume requirements can serve as a framework to uphold procedural excellence while ensuring patients everywhere have access to safe, effective transcatheter tricuspid valve interventions. Finding the right balance will require collaboration between medical professionals, health systems, and policymakers, but the ultimate goal remains clear – delivering the highest quality care to those who need it most.

Qualification to Initiate a T-TEER Program	
Open Heart Surgeries	≥50 in the previous year prior to T-TEER program initiation
Tricuspid Valve Surgeries	≥20 in the 2 years prior to T-TEER program initiation
Physicians with Cardiac Surgery Privileges	≥2
Physician with Interventional Cardiology Privileges	≥1
Cardiac Electrophysiologist	1 board certified, eligible, or equivalent available for pacemaker implantation or lead extraction when required
TAVR and TEER Procedures	≥50 TAVR and ≥20 TEER per year or ≥100 TAVR and ≥40 TEER over the previous 2 years (Bass et al., 2023 ACC/AHA/SCAI advanced training statement on interventional cardiology (coronary, peripheral vascular, and structural heart interventions): A report of the ACC Competency Management Committee.)
Complete Transesophageal Echocardiograms (TEE)	≥200 per year or ≥400 over the previous 2 years (Wiegers et al., ACC/AHA/ASE Advanced Training Statement on Echocardiography. 2019; Little et al., Recommendations for Special Competency in Echocardiographic Guidance of Structural Heart Disease Interventions: From the American Society of Echocardiography. 2023)

Qualifications to maintain a T-TEER Program	
Tricuspid Valve Interventions	≥20 tricuspid valve interventions (transcatheter or surgical) of which ≥10 are transcatheter over 1 year, or ≥40 tricuspid valve intervention (transcatheter or surgical) of which ≥20 are transcatheter over 2 years
Specialty Expertise	The initial complement of specialty expertise must be maintained
Transcatheter Structural Cases	≥50 per year or ≥100 over the previous 2 years

Operator Requirements	
Primary Catheter Operator	- ≥50 career structural valve procedures), of which ≥20 are TEER procedures (Bass et al., 2023)
	- Board eligible, equivalent, or certified in either interventional cardiology or cardiothoracic surgery
	- Certification of device-specific training
Interventional Echocardiographer	- ≥50 career structural valve disease procedures, of which ≥20 are TEER procedures
	- Level 3 or equivalent board eligibility or certification in echocardiography
	- Certification of device-specific training

Registry Requirement

The societies recommend that the heart team and hospital participate in a prospective, national, audited registry. The success of the STS/ACC TVT registry is well-established. Mandatory reporting to the STS/ACC TVT registry under CED through a supplementary module will facilitate post-market surveillance, long-term outcome measurement, and comparative effectiveness research for this still nascent breakthrough emerging technology. This supplementary module, developed by the STS and ACC with input from specialty societies and other stakeholders, will enhance the existing TVT registry for TAVR and mitral valve TEER systems. Emphasizing the importance of obtaining complete one-year outcomes data, including patient-reported outcomes, is crucial.

Participation in society-run registries is essential for several reasons:

1. Real-World Insights: These registries capture data from routine clinical practice, providing insights into how treatments and interventions perform outside the controlled environment

of clinical trials. This real-world relevance is vital for understanding the practical effectiveness of medical procedures and treatments.

2. Longitudinal Data: Society-run registries often track patients over long periods, allowing for the collection of longitudinal data. This data reveals trends and long-term outcomes, which are valuable for assessing the effectiveness and safety of treatments over time, as well as determining if a treatment is reasonable and necessary.
3. Diverse Data: By including data from a wide range of institutions and patient populations, the TVT registry provides a comprehensive picture of how treatments work across different demographics and clinical settings. This diversity ensures that the findings are applicable to a broad spectrum of patients.

Over the past decade, the STS/ACC TVT Registry and Coordinated Registry Network have supported 23 regulatory decisions and ensured the evidence-based evaluation of transcatheter valve therapy (TVT) technology. When TAVR was first approved under the NCD with CED in 2012, it was limited to high-risk patients who were too compromised to undergo open heart surgery for surgical aortic valve replacement (SAVR). Over time, data collected through the registry provided evidence demonstrating the safety and efficacy of the procedure, thereby enabling intermediate and low-risk populations to benefit from this once novel therapy. This method of evidence generation creates significant value for manufacturers and the broader device ecosystem, with substantial benefits to public health. Additionally, this model of data collection through the STS/ACC TVT Registry sets the standard for newer technologies, such as T-TEER.

Overall, participation in these registries is vital for advancing medical knowledge and improving healthcare delivery, especially as new technologies emerge. The robust governance structures and auditing strategy of these registries ensure transparency and accountability, enhancing the credibility of the evidence generated and making it a reliable source for informing medical practice and policy.

CED Study Requirements

The societies are supportive of a CED study. We believe that in addition to standard measures of disease severity, it would be important to provide provisions for the TVT registry to broaden their data elements and require appropriate clinical, imaging (echocardiographic and computed tomography) and hemodynamic parameters. Without a comprehensive and accurate data registry, the goal of learning about relevant subgroups and their outcomes in the CED, will not be possible. Considering the numerous challenges associated with requesting an extremely comprehensive and robust data set—including capturing, storing, and analyzing such data –we are committed to assisting CMS and the trial sponsors by offering our expertise in all aspects of CED studies.

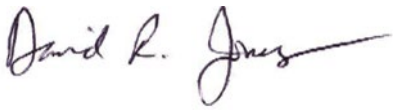
The STS/ACC TVT Registry was aware of the intent by one device manufacturer to leverage the registry data but was not involved in the development of the evidence development plan, which is concerning. Historically, a letter of support from the societies would have been required as part of the application process associated with other types of initiatives to list the trial on clinicaltrials.gov if the societies were not themselves the sponsor. This new CED process appears to bypass that requirement during protocol review and approval, which could present issues. If society-run

registries are being utilized for the CED study and in the evidence development plan, it is crucial to engage us in the earlier phases of the CED development process to ensure comprehensive and effective protocol development as well as providing enough time for necessary registry updates to best support and achieve device manufacturers' CED study needs.

Another concern of the societies is the requirement of an active contemporaneous comparator cohort. Use of large, aggregated health systems databases and/or claims data linked to electronic health records may provide this comparator with important known limitations: lack of standardized data collection, lack of data quality control, lack of consistent active follow-up, potential for bias in the setting of missing data. In addition, the medical management of tricuspid regurgitation continues to evolve, introducing temporal bias which should be mitigated in the data collection. These limitations may result in significant bias in the results of between group outcomes.

The societies thank CMS for the opportunity to provide comment on the proposed decision memo for the T-TEER NCD. The societies are largely supportive of the proposal for Medicare coverage 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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