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RE: CAG-00467N, Proposed Decision Memo for Transcatheter Tricuspid Valve Replacement

The American Association for Thoracic Surgery (AATS), American College of Cardiology (ACC), American Society of Echocardiography (ASE), Heart Rhythm Society (HRS), Society for Cardiovascular Angiography and Interventions (SCAI) and 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 transcatheter tricuspid valve replacement (TTVR) and surgical tricuspid valve (TV) replacement procedures. The societies are supportive of a National Coverage Determination (NCD) for TTVR for patients with symptomatic tricuspid regurgitation graded as at least severe, under coverage with evidence development (CED). We appreciate the opportunity to comment on the proposed decision memo.

The societies are broadly supportive of the proposed decision memo for TTVR Medicare coverage with 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 the operator and institutional criteria previously recommended, as there is strong evidence supporting this approach based on successful experiences with transcatheter aortic valve replacement (TAVR) and mitral procedures. 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 TTVR is guided by robust evidence and best practices, ultimately benefiting patients by providing timely access to care while achieving optimal outcomes.

Operator and Facility Requirements

We support the general direction of the conditions of coverage outlined in the proposed decision memo. Care of TTVR patients should be guided by a multidisciplinary heart team (MDHT) with experience in the care and treatment of tricuspid regurgitation. However, the societies stand by our previous recommendations for operator and institutional volume requirements in order to optimize outcomes at new transcatheter TV interventional programs.

TTVR should be performed in hospitals equipped with the necessary infrastructure. The hospital must have an active cardiac surgery program with at least two cardiac surgeons experienced in treating valvular heart disease (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 TTVR must have access to a cardiac catheterization lab and an interventional/implantation suite. Operators need access to advanced imaging, including cine fluoroscopy and 2D/3D TEE during TTVR, and access to 2D/3D intracardiac echocardiography (ICE) is highly recommended. Rapid access to a cardiac electrophysiologist skilled in leadless pacemaker placement, and coronary sinus lead placement is also necessary. Availability of a cardiac electrophysiologist with guideline-recommended experience and skills for lead extraction is also required. In addition to the interventional echocardiographer, TTVR care facilities must have an echocardiographer trained in the quantitation of TR severity, identification of TR etiology and understanding of risk assessment using 2D/3D transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE). Furthermore, institutions participating in TTVR must have access to advanced cardiopulmonary support such as extracorporeal membrane oxygenation and/or ventricular support devices.

These complex procedures should only be performed at institutions that regularly conduct surgical TV operations and participate in the STS Adult Cardiac Surgical Database, where procedural outcomes can be monitored on a real-time dashboard offering comparisons to like facilities across the nation, thus ensuring targeted insights into the care provided are available to the clinical team. Similarly, only institutions with established interventional cardiology programs in PCI, balloon valvuloplasty, TAVR, mitral transcatheter edge-to-edge repair (M-TEER), catheter closure of

periprosthetic leaks, and septal closure device deployment should offer transcatheter TV interventions.

The interventional echocardiographer, interventional cardiologist and surgeon will need to have appropriate training and experience in structural heart interventions in order to establish a TTVR program. Following the establishment of a program, all members of the multidisciplinary team will need to maintain minimal volume requirements for continued participation and will be monitored on an ongoing basis to ensure acceptable outcomes as defined by the Societies' criteria.

Operator training is a crucial component for treating structural/valvular heart disease using a transcatheter approach. Construction of a training curriculum encompassing pre-procedural, clinical, imaging, procedural and post-procedural elements is essential. Criteria for fellowship and postgraduate training will be established by the participating Societies in an expert consensus statement currently under development.

The societies do maintain that due to the complexity of the TTVR procedure, that three physician operators should actively participate in the procedure until the institution can demonstrate consistent procedural safety as outlined below:

1. An interventional echocardiographer should be considered a co-operator for TTVR and must provide imaging expertise in patient and device selection as well as catheter position and device deployment. The interventional echocardiographer will not also provide anesthesia during the procedure.

2. An interventional cardiologist must provide expertise in vascular access, catheter management, wire manipulation, and device deployment.

3. A cardiac surgeon skilled in transcatheter valve procedures must provide additional expertise in catheter management, wire manipulation, and device deployment, as well as intra-procedural complication management.

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 TTVR institutions must submit complete data to the STS/ACC TVT Registry.

The joint 3 specialty physician composition of the intra-procedural team can be reconsidered by the institution after consistent demonstration of procedural safety with a 30-day major complication rate of <20% (composite of CV death, severe bleeding, non-elective TV re-intervention, and major access/vascular/cardiac structural complications) as documented in the STS/ACC TVT Registry following a minimum of 25 cases or 3-years of TTVR procedures. Upon meeting these safety and quality requirements, the composition of the team working as co-operators may be adjusted to an interventional echocardiographer (who must provide imaging expertise during all aspects of the procedure (and may not also provide anesthesia services), and one other procedural co-operator skilled in transcatheter procedures with device-specific training, who may be interventional cardiologists or cardiac

surgeons with appropriate board certification. After achieving this initial minimal safety and quality threshold, TTVR institutions must demonstrate maintenance of this threshold of <20% complication rate as documented by the STS/ACC TVT Registry on an annual basis. Institutions not achieving this minimum annual threshold of safety and quality should revert to the original 3 operator until such time this quality threshold can be maintained for 3 consecutive years.

Current and future technologies for TTVR should require collaborative participation by the cardiologist, surgeon, and interventional echocardiographer. 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.

As mentioned in the decision memo, strong evidence for volume requirements in TTVR procedures is currently lacking and, to date, the societies have not published peer-reviewed guidance on facility and operator requirements for transcatheter TV interventions. However, 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). In addition, the 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). 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. 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).

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 TTVR procedures. 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 TTVR procedures are performed safely and effectively, providing the best possible care for patients with severe tricuspid regurgitation.

While the societies have suggested the following facility volume requirements to ensure quality standards and outcomes, we appreciate the inclusion of determining appropriate volume requirements based on findings in the Coverage with Evidence Development (CED) study. This approach allows for a data-driven determination of the optimal volume thresholds, ensuring that the standards set are both evidence-based and conducive to achieving the best possible patient outcomes.

Qualification to Initiate a TTVR Program	
Open Heart Surgeries	≥50 in the previous year prior to TTVR program initiation
Tricuspid Valve Surgeries	≥20 in the 2 years prior to TTVR 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	≥100 TAVR and ≥20 TEER per year or ≥200 TAVR and ≥40 TEER over the previous 2 years (STS/ACC TVT Registry Analysis)
Complete Transesophageal Echocardiograms (TEE)	≥200 per year or ≥400 over the previous 2 years (Wiegers et al., 2019; Little et al., 2023)

Qualifications to maintain a TTVR Program	
Tricuspid Valve Interventions	≥20 (transcatheter or surgical) of which ≥10 are transcatheter and ≥5 are TTVR in 1 year, or ≥40 (transcatheter or surgical) of which ≥20 are transcatheter and ≥10 are TTVR 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 (Bass et al., 2023), of which ≥25 are TEER procedures
	- Board eligibile, equivalent, or certified in either interventional cardiology or cardiothoracic surgery
	- Certification of device-specific training

Operator Requirements	
Interventional Echocardiographer	- ≥50 career structural valve disease procedures, of which ≥25 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 TTVR.

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, though the new CED structure does raise some questions.

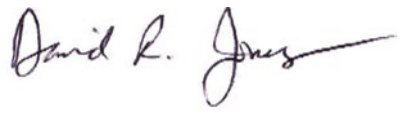
1. How can we ensure that the correct patients are accurately identified for inclusion in the study with the resources available?
2. How can ensure that patients receiving TTVR truly have severe TR despite optimal medical therapy given the dynamic nature of the degree of regurgitation and the difficulty of achieving optimal imaging quality outside of experienced institutions?
3. How can we accurately compare the outcomes of patients with severe, massive, and torrential TR given the nuances of quantification?
4. Without proper training, is there a risk of treating moderate TR instead of severe TR, as specified in the proposed NCD? Verifying and documenting severe tricuspid regurgitation presents challenges in clinical practice. We are concerned that for facilities without adequate resources, and highly trained imagers, it may be challenging to ensure severe TR patients are identified to meet the study's requirements and generate meaningful data. Including only patients with symptomatic TR graded as at least severe ensures the integrity and validity of the study outcomes. It allows for a clear assessment of the TTVR's effectiveness and safety in the intended patient population.
5. The proposed NCD lists several areas of interest, including patient populations not included in the trial, such as those with pulmonary hypertension and left ventricle dysfunction. How can we ensure that study sponsors adequately capture this information accurately and comprehensively?
6. We also respectfully question the feasibility of including active comparators in the study design. The use of an active comparators is crucial for providing a more accurate assessment of the intervention's effectiveness by comparing untreated patients with the same condition. Without this context, it is not possible to determine effectiveness of the study treatment. How can we ensure that the cohort is matched appropriately to have a real comparator, given the heterogeneity of the severe TR population especially quantifying the severity of TR from claims data sources? Obtaining a precise comparator to evaluate study outcomes using real-world evidence is particularly challenging. We encourage CMS and the sponsor to be as stringent as possible in determining what constitutes an accurate active comparator.

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.

By addressing these queries, CMS and the study sponsors can ensure that the CED study produces robust and reliable evidence to inform future clinical practice and policy decisions. 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 societies thank CMS for the opportunity to provide comment on the proposed decision memo for the TTVR 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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