July 19, 2024

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

RE: National Coverage Analysis for Transcatheter Tricuspid Valve Replacement

Dear Ms. Syrek-Jensen:

The American Association for Thoracic Surgery (AATS), Association of Black Cardiologists (ABC), 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 the development of a National Coverage Determination (NCD) for TTVR and we appreciate the opportunity to comment on the National Coverage Analysis (NCA).

Transcatheter tricuspid valve replacement (TTVR) represents an emerging technology to treat severe TR. Candidates for this technology have tricuspid valve disease severe enough to cause symptoms despite optimal medical therapy and are at intermediate or greater risk for TV surgery. During a TTVR procedure, a bioprosthetic valve is implanted in the TV annulus using a catheter via a transfemoral venous approach.

The EVOQUE tricuspid valve replacement system is currently the sole TTVR device approved by the U.S. Food and Drug Administration (FDA). The EVOQUE device is indicated for use for the improvement of health status in patients with symptomatic severe TR despite being treated optimally with medical therapy and for whom TV replacement is deemed appropriate by a Heart Team. The undersigned organizations recommend that CMS cover TTVR for the treatment of TR when performed according to the FDA-approved indication. Non-approved indications should only be performed within a clinical study.

The Multidisciplinary Heart Team (MDHT)

The universal adoption of multi-disciplinary heart teams (MDHT) in cardiovascular medicine and surgery derives from their established role in the care of patients undergoing cardiac transplantation and/or mechanical support, as well as from their demonstrated value in a pivotal trial of percutaneous coronary intervention versus coronary artery bypass grafting for patients with severe coronary artery disease (Serruys et al., 2009). The MDHT is a foundational element of the institutional requirements for the establishment of transcatheter programs for the treatment of patients with aortic stenosis and mitral regurgitation (Bavaria et al., 2018; Nishimura et al., 2019; Bonow et al., 2019) The 2020 AHA/ACC guidelines for the management of patients with valvular heart disease (VHD) include a Class 1 recommendation for evaluation by a MDHT when intervention is considered (Otto et al., 2021). In addition, referral to a comprehensive heart valve center (Nishimura et al., 2019) is preferred when treatment options are being considered for asymptomatic patients with severe VHD, patients who may benefit from repair versus valve replacement, and for patients with multiple co-morbidities.

Given the high prevalence of secondary TR, patients with this disease often present with multiple co-morbidities which must be considered by the MDHT. For patients with TV disease, we recommend minimum requirements for MDHT membership (Table 1) include a general or valve cardiologist, heart failure specialist, multi-modality imaging specialists (echo, CT, MR), interventional echocardiographer, interventional cardiologist, electrophysiologist, cardiac surgeon, cardiac anesthesiologist, advanced practice providers, program navigator, structural heart coordinator, and data manager. Additional specialists, including geriatricians, stroke neurologists, nephrologists, hepatologists, hematologists, nutrition counselors, rehabilitation experts, and social workers may need to be included as part of the MDHT in specific circumstances.

Table 1. MDHT Requirements for Tricuspid Valve Intervention
General/valve cardiologist
Heart failure specialist
Multi-modality imaging specialists: Echocardiography, Computed Tomography, Magnetic Resonance
Interventional echocardiographer
Interventional cardiologist
Cardiac surgeon
Electrophysiologist
Cardiac anesthesiologist
Advanced practice providers
Program navigator
Structural heart coordinator
Data manager
Other*

* The MDHT may require the inclusion of additional specialists such as geriatricians, stroke neurologist, nephrologist, hepatologist, hematologists, nutrition counselors, rehabilitation experts, and social workers.

Evaluation by the MDHT is an obligate step in the patent's journey, as mandated by best practices and regulatory authorities. The team should meet regularly (preferably weekly) to review case histories, imaging findings and other pertinent studies, determine procedural risk, achieve consensus on management recommendations, review outcomes, assess quality, and verify reporting. Patient's individual needs and preferences should be emphasized. Ideally, the MDHT approach will leverage the combined experience and expertise of the group and lead to more standardized and evidence-based decision-making. The general/valve cardiologist is usually responsible for the initial referral to the MDHT and longer-term follow-up and communication. For patients being considered for the treatment of severe TR, it is particularly important to ensure optimization of heart failure management which may include interventions for both reduced and preserved ejection fraction phenotypes. Concomitant valvular heart disease is also common in these patients treatment of which may secondarily reduce the severity of TR. Patients with TR frequently develop atrial fibrillation or have prior cardiac implanted electronic device (CIED) leads thus obligating the MDHT to consider rhythm management and the specific challenges imposed by the presence of indwelling CIED leads or the need for a new CIED. Integration of imaging data across modalities is essential for procedural planning. A dedicated and trained intra-procedural echocardiographer must be a part of the MDHT since their integral role in guidance and selection cannot be overemphasized. As indicated by the Request for TTVR Medicare National Coverage Determination by Edwards Lifesciences (page 19), "In the context of the TRISCEND II trial, an interventional cardiologist and cardiac surgeon frequently performed the intra-operative components of the procedure, which was appropriate given the procedures were performed as a part of a clinical trial." The physicians who are present during the performance of the procedure will demonstrate the knowledge and skill necessary to accomplish the technical aspects of transcatheter or surgical device deployment safely and effectively and

participate in post-procedural patient management. Each physician directly participating in the procedure has the responsibility to ensure optimal patient outcomes.

Risk-Benefit Analysis of TTVR

It is important for the MDHT to consider a number of factors when determining the appropriateness, possible benefits, and risks from TTVR for any given patient. The FDA indication for use of the EVOQUE device is to improve health status in patients with symptomatic, severe TR despite optimal medical therapy (OMT), for whom TV replacement is deemed appropriate by a heart team. The first consideration is the definition of OMT. Although the TRISCEND II Trial showed a benefit in health status measures compared to OMT, such treatment was not prescriptive nor well-defined given the lack of Class I level of recommendations for medical management of TR (Otto et al, 2021). In addition, OMT continues to evolve as more is learned about the relationship between TR and the medical/device management of heart failure, as well as of atrial fibrillation (Adamo et al., 2024). TR reduction is observed following reduction of mitral regurgitation (Adamo et al, 2022), after cardiac resynchronization therapy (Stassen et al., 2022). TR is also reduced in many AF patients with rhythm control interventions (Soulat-Dufour et al, 2022). Given the relationship between heart failure with preserved ejection fraction and TR (Muraru et al., 2024; Hahn et al., 2024), the effectiveness of sodium glucose cotransporter-2 (SGLT2) inhibitors in reducing the progression of severity of TR is an area of active investigation. Studies suggest that this class of drugs improves right ventricular function and reduces peak TR velocities (Mustapic et al., 2022). Randomized control trials assessing the effect of SGLT2 inhibitors on TR are underway (NCT06027307 and NCT056866160). Clinicians should be aware of this changing medical landscape and consult with advanced heart failure experts prior to consideration of interventional therapy.

Second, device therapy is recommended for patients with severe, symptomatic TR. A recent study has shown that whereas TR progresses in approximately 20% of patients over 2 years, it may regress in up to 38% of patients (Bolumburu et al., 2024), evidence of the protean and dynamic nature of this disease and the need for consistent follow-up prior to referral for interventional therapy. In addition, quantitation of TR is both challenging and nuanced. Adjudication required centralized core lab assessment within the TRISCEND II trial. Recent consensus documents have described current quantitative methods for assessing TR (Hahn et al., 2023) and studies show health benefits increase with each TR grade reduction following transcatheter repair with the greatest improvement seen in patients with low baseline health status (Arnold et al., 2024a; Arnold et al., 2024b). Thus it is likely that the greatest benefit will be seen in patients with severe or greater TR. Assessment of both baseline health status and TR severity should be performed by the MDHT prior to consideration of advanced therapies.

Third, the MDHT determination of the appropriateness of tricuspid valve replacement necessarily involves the consideration of isolated TV surgery, which is the only current guideline recommended intervention(Otto et al., 2021). Although current studies continue to show relatively high surgical mortality (~7%) and morbidity (~11% pacemaker rates) in the elderly and co-morbid patient

population presenting for operation, these rates may be decreasing as awareness of the disease increases, patients are referred earlier in their disease process, and new surgical techniques are adopted (Shih et al., 2023; Russo et al., 2022; Yang et al., 2021; Thourani et al., 2024). A number of prior surgical risk scores have been published (Dreyfus et al., 2021; LaPar et al., 2018; Wang et al., 2022;) and a recent risk score and online risk calculator for isolated tricuspid surgery by the STS have been developed (Thourani et al., 2024), some of which may be predictive of outcomes for transcatheter repair technologies (Omran et al., 2022; Adamo et al., 2024) and thus may help with the shared decision-making process.

Finally, a risk-benefit assessment of TTVR must be performed by the MDHT. In the as-treated population of patients undergoing TTVR, the 30 day composite major adverse events (MAEs) reported in the FDA Summary of Safety and Effectiveness Data (SSED) was 27.4% and included among other outcomes, a 3.2% cardiovascular mortality, 10.2% severe bleeding (defined as fatal, life-threatening, extensive or major bleeding), and a 14.7% rate of arrhythmia and conduction disorder requiring permanent pacemaker. In addition to MAEs, 57 serious adverse events were also reported. These risks must be balanced against the main reported benefits of TTVR, namely, improvement in quality of life and symptom burden.

One additional co-morbidity seen in the symptomatic, severe TR population is worth mentioning. Although the Request for TTVR Medicare NCD states that patients with pre-existing cardiac electronic devices (CIEDs) are appropriate candidates for this therapy, concerns have been raised about the safety of this practice. In the as-treated population of patients undergoing TTVR, >35% of patients receiving the EVOQUE device had CIED leads across the tricuspid valve; these leads were "jailed" against the native annulus by the TTVR. Given the likely inability to extract jailed leads if indicated (eg, in the setting of lead/pacer pocket infection or lead malfunction), the electrophysiologist on the heart team plays an essential role in determining risk of future complications, likelihood of successful/effective lead extraction, feasibility of alternative pacing methods, as well need for placement of new CIEDs (Hahn et al., 2024). The MDHT discussion should include consideration of transcatheter devices that may not jail the CIED lead. Follow-up of the patients with prior CIED and trans-tricuspid valve leads within the trial and during commercial use is critical and should require periodic interrogation of jailed leads to further identify risks of this procedure.

Patient Evaluation

Each patient's suitability for surgical tricuspid valve intervention, transcatheter intervention, or palliative therapy must be evaluated and documented collaboratively by the MDHT. This collaboration includes discussions among an interventional echocardiographer, interventional cardiologist, and cardiac surgeon with experience in the care and treatment of TR and may also include a heart failure specialist, an electrophysiologist and other specialists as needed. The evaluation for TV surgical or transcatheter intervention must take place only after optimization of medical therapies.

For accurate diagnosis, prognosis, and effective planning of TV therapy, it is essential to perform multimodality cardiac imaging that specifically targets the anatomy and function of the TV apparatus, right-side chambers, and adjacent structures (Cammalleri et al., 2021).

The interventional echocardiographer is expected to evaluate the mechanism and confirm severity of TR (Zoghbi et al., 2017; Hahn et al, 2023) to consider the anatomic and functional criteria which may determine the appropriateness of TTVR, to consider all possible therapies (medical, transcatheter, surgical, or palliative) and to discuss those anatomic and functional considerations in detail with the MDHT.

Facility Infrastructure Requirements

TTVR must be furnished in a hospital 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 recommendation parallels the "2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacements for Transcatheter Aortic Valve Replacement" (Bavaria et al., 2020). Additionally, paralleling the recommendations for transcatheter mitral valve interventions (Bonow et al., 2019) institutions must have at least 1 interventional echocardiographer with level 3-training and National Board of Echocardiography certification, or a cardiac anesthesiologists with training and experience in the acquisition and quantitative interpretation of TTE, TEE, and 3D TEE studies in patients with TR.

The need for patient facilities sufficient to allow high-quality preprocedural/postprocedural care with personnel experienced in managing patients who have undergone open-heart procedures and MHDT consultation is self-evident. Implanting physicians must have prompt access to facilities with the necessary equipment, including a cardiac catheterization laboratory and an interventional/implantation suite. Appropriate office space for the medical, nursing, and technical personnel involved is also required, preferably in a central setting. Ancillary testing facilities (pulmonary function, echocardiography, vascular duplex scanning, clinical laboratory, CT) should be of high quality, ideally accredited by the appropriate certifying organization, and able to accommodate the patient load in a timely manner. Operators must have access to advanced imaging, including cine fluoroscopy and 2D/3D transesophageal echocardiography (TEE) throughout the TTVR 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, and deployment of septal closure devices, with outcomes that equal or exceed those established nationally for similar procedures, should offer transcatheter TV intervention.

Qualifications to begin a TTVR program for facilities without TTVR experience.

Important issues to consider in the establishment of a transcatheter TV intervention program are the size and spectrum of the clinical referral base needed to ensure an adequate number of patients to provide for the viability of the program. Below are the recommended requirements to start TTVR intervention programs. The current proposed case volumes for TTVR pertain to the use of the EVOQUE tricuspid valve replacement system for the improvement of health status in patients with symptomatic, severe TR despite optimal medical therapy, for whom TV replacement is deemed appropriate by a heart team. Intervention for TR is a rapidly evolving field and recommended case volumes for transcatheter TV repair and replacement systems that may become available in the future may differ. Introduction of this technology across communities must also take into account the well-recognized barriers faced by women, under-represented racial and ethnic groups, and persons living in rural areas to surgical and trans-catheter cardiac interventions. The case volumes reflect an expert consensus that strikes a balance across procedural quality, expected outcomes, and patient access. They are readily achievable for many sites and should not be considered exclusionary. Minimum case volume requirements reflect the process, infrastructure, and commitment needed for a successful, competent program but are not necessarily sufficient for expertise.

The program case volumes recommended were obtained by querying the STS Adult Cardiac Surgery Database, the STS/ACC TVT Registry, reviewing the published experiences of other data sources, and soliciting expert opinion. The proposed requirements are constructed to: 1) ensure patient safety and promote quality; 2) demonstrate that there is commitment on the part of the institution to the structural heart disease program; and 3) use existing volume as surrogate for an established TTVR program to ensure adequate experience for the maintenance of a sustainable TV intervention program.

To initiate a TTVR program in hospitals without prior TTVR experience, the hospital program must meet the following qualifications:

a) ≥50 open heart surgeries in the previous year prior to the TTVR program initiation, and;
b) ≥20 tricuspid valve surgeries in the 2 years prior to TTVR program initiation, and;
c) ≥2 physicians with cardiac surgery privileges, and;
d) ≥1 physician with interventional cardiology privileges, and;
e) 1 board certified/board-eligible cardiac electrophysiologist available for pacemaker implantation or lead extraction when required, and;
f) ≥100 TAVR and ≥20 TEER procedures per year or ≥200 TAVR and ≥40 TEER over the previous 2 years (STS/ACC TVT Registry Analysis)
g) ≥200 complete TEE performed per year or ≥400 complete TEE performed over the previous 2 years (Wiegers et al., 2019; Little et al., 2023)

Both the interventional cardiologist and surgeon will need to have appropriate training 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 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.

Defining minimum operator and institutional requirements for these therapies is an important first step to ensuring their optimal implementation. Several of the TTVR competencies recommended parallel those included in the "2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement," (Bavaria et al., 2019) and the "2019 AATS/ACC/SCAI/STST Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention," (Bonow et al. 2020) although many are specific to TV interventions.

Operator Requirements

To optimize outcomes at a new TTVR intervention program, the primary catheter operator (interventional cardiologist or surgeon) should document:

- ≥50 career structural valve procedures (Bass et al., 2023), of which ≥25 are TEER procedures
- Board eligibility or certification in either interventional cardiology or cardiothoracic surgery
- Certification of device-specific training.

To optimize outcomes at a new TTVR intervention program, the interventional echocardiographer should document:

- ≥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

<u>Requirements for the Intraoperative Technical Aspects of TTVR</u>

At the initiation of a TTVR program, three physician operators will actively participate in the TTVR procedure:

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 an 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 composition until such time this quality threshold can be maintained for 3 consecutive years.

Qualifications to Maintain a TTVR Program

To optimize outcomes at a TTVR program, sites with TTVR experience should maintain the following:

a) ≥20 tricuspid valve interventions(transcatheter or surgical) of which ≥10 are transcatheter and of which ≥5 are TTVR in 1 year, or ≥40 tricuspid valve intervention (transcatheter or surgical) of which ≥20 are transcatheter and of which ≥10 are TTVR over 2 years, and;
b) The initial complement of specialty expertise must be maintained, and;
c) ≥50 transcatheter structural cases per year or ≥100 over the previous 2 years.

Registry/ CED Requirements

Coverage with Evidence Development (CED) is an extremely powerful mechanism offering significant value to payers, clinicians, and patients. CED has been demonstrated to be an ingenious technique allowing the diffusion of diverse innovative cardiovascular technologies and services into the marketplace while simultaneously promoting timely clinical safety and effectiveness evaluations.

The societies support the use of CED to provide Medicare beneficiaries with prompt access to new technologies and services when early evidence suggests, but does not yet convincingly demonstrate, a net benefit for beneficiaries.

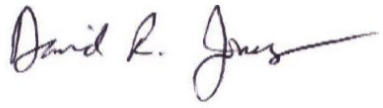
The success of the combined STS and ACC TVT registry is established. Mandatory reporting to the STS/ACC TVT registry under CED through a supplementary module will allow for post-market surveillance, long-term outcome measurement, and comparative effectiveness research. The registry module to supplement the existing TVT registry for TAVR and mitral valve TEER system will be developed by the STS and ACC in conjunction with input from specialty societies and other relevant stakeholders. The importance of obtaining completeness of one year outcomes data including patient reported outcomes must be emphasized.

Use of drug or device subject to FDA regulations and the status of current FDA regulatory review

While the EVOQUE system by Edwards' is the only FDA-approved device for the treatment of TR via TTVR at this time, there is much research and development emerging in this space. Devices currently in development include Intrepid (Medtronic), LuX-Valve (Jenscare Biotechnology), GATE (Navigate Cardiac Structures, Inc.), Topaz (TriCares), VDYNE valve (VDYNE), and TRISOL Valve (Trisol Medical). With many emerging technologies on the horizon in the tricuspid valve replacement space, the societies recommend that the developed NCD extend to future devices that use similar technology and fall within the same device class. This approach ensures that the NCD remains relevant and applicable as new technologies receive FDA-approval, supporting ongoing advances in TR management using transcatheter tricuspid valve replacement.

The societies support Medicare coverage for TTVR along with recommended facility and operator requirements, including CED. We thank CMS for the opportunity to provide comment on the NCA. 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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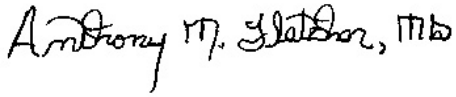

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