



May 2, 2025

Administrator Mehmet Oz  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Oz,

As members of the Heart Valve Disease Policy Task Force, a national group of 30 leaders including clinician and patient advocacy organizations, we appreciate the opportunity to comment on CMS's proposed NCD regarding Tricuspid Valve Transcatheter Edge-to-Edge Repair (T-TEER), also known as the [TriClip G4 System](#). We wish to emphasize the critical importance of establishing a comprehensive Medicare coverage policy that includes all FDA-approved minimally invasive transcatheter therapies for patients with symptomatic severe tricuspid regurgitation (TR).

A broad and inclusive coverage framework is essential to ensure timely access to innovative treatments – such as T-TEER – that have demonstrated meaningful improvements in quality of life, functional capacity, and reduced hospitalizations. This is especially vital for patients living with heart valve disease, where early intervention can help preserve independence, prevent disease progression, and ultimately reduce the burden on the healthcare system.

Patients treated with T-TEER have consistently shown improvements in quality of life and reduced hospitalizations. These outcomes are clinically meaningful and directly impact patients' ability to remain active and independent, while avoiding repeated hospital stays and disease progression. Patients with symptomatic TR often face debilitating fatigue, shortness of breath, and repeated hospitalizations that severely limit their independence and quality of life. T-TEER offers hope for these patients – it allows them to regain control of their lives and live to their fullest potential.

We applaud the growing recognition of T-TEER as an important advancement in the treatment of symptomatic tricuspid regurgitation. T-TEER has shown clinically meaningful and sustained improvements in patients' daily function, quality of life, and ability to remain active in their communities. According to two-year follow-up data from the TRILUMINATE trial, patients treated with T-TEER reported sustained improvements in New York Heart Association (NYHA) functional class, Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, and significant reductions in heart failure hospitalizations.<sup>1</sup> These outcomes are much more than numbers; they represent hundreds of patients who have been able to spend more time with their loved ones, stay out of the hospital, and have the freedom to live their lives. This trial data further demonstrates the need for timely access to T-TEER.

We agree that involving a multidisciplinary heart team is vital for patient-centered evaluation. However, we encourage CMS to reconsider the inclusion of an electrophysiologist (EP) as a required heart team

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<sup>1</sup> Kar, Saibal, et al. "Two-Year Outcomes of Transcatheter Edge-To-Edge Repair for Severe Tricuspid Regurgitation: The TRILUMINATE Pivotal Randomized Trial." *Circulation*, 30 Mar. 2025, <https://doi.org/10.1161/circulationaha.125.074536>.

member. While EPs are essential in other structural heart contexts, they are not central to the T-TEER procedure or the assessment and management of TR. Requiring an EP may place unnecessary burdens on programs, particularly in rural and underserved areas, potentially limiting access to care.

Individualized decision-making by an experienced Heart Team is key to ensuring patients receive care aligned with their medical needs, preferences, and life goals. We strongly support CMS's emphasis on shared decision-making and encourage continued focus on equitable and patient-centered approaches.

T-TEER is a minimally invasive, catheter-based procedure that does not require open-heart surgery, making it a safer and more accessible option for medically complex patients. Patients should not be denied access to this evidence-based therapy based on precautionary measures that do not reflect the nature of the procedure. The coverage policy should reflect the real-world delivery of care and prioritize equitable access.

In conclusion, we appreciate and strongly advocate for an inclusive and forward-thinking coverage policy that prioritizes patient access and upholds the principles of patient-centered care to minimally invasive tricuspid valve regurgitation treatment. We appreciate the opportunity to provide input and look forward to working collaboratively with CMS to advance patient-centered policies.

Thank you for your attention to this important issue.

Sincerely,

The Heart Valve Disease Policy Task Force

Alliance for Patient Access  
Caregiver Action Network  
Conquering CHD  
HealthyWomen  
Heart Valve Voice U.S.  
Hypertrophic Cardiomyopathy Association  
Men's Health Network  
The Mended Hearts, Inc.  
Partnership to Advance Cardiovascular Health  
Preventive Cardiovascular Nurses Association  
RetireSafe