



October 28, 2024

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure,

On behalf of Heart Valve Voice US, a national non-profit patient advocacy organization dedicated to enhancing the lives of individuals affected by heart valve disease, I want to express our gratitude for the opportunity to comment on the NCA Tracking Sheet regarding Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER), also known as TriClip. As an organization deeply committed to patient-centered advocacy, HVV-US has a unique perspective to share regarding the lived experiences of patients with heart valve disease and the promise that breakthrough technologies hold. Recent advancements in transcatheter tricuspid therapies, such as TriClip, offer new possibilities for patients who might otherwise face more invasive treatment options. In light of this, HVV-US is hopeful that CMS will provide timely and adequate coverage for these innovative devices.

The lived experiences of our community members are paramount in our advocacy for these treatments. Before the FDA approval of TriClip, the field of tricuspid valve regurgitation had historically offered limited treatment options. A Tennessee patient named Gayle has a story that exemplifies the profound positive impact that the TriClip device has had on her quality of life and the potential benefits for many others living with heart valve disease.

In 2012, Gayle, a 68-year-old woman, began experiencing irregular heart rhythms and was diagnosed with AFib. During this process, her doctors discovered issues with her tricuspid valve and diagnosed her with tricuspid regurgitation. At that time, her only option was open-heart surgery to replace the valve—a path she was not ready to take. However, her symptoms continued to worsen. As an avid hiker, she could no longer keep pace with her husband; she experienced shortness of breath, and her AFib worsened despite medication. Even visiting her daughter and granddaughter in Santa Fe became a struggle, as her body could not tolerate the increased altitude.

Eventually, the exhaustion from her damaged tricuspid valve became unbearable. She returned to her cardiologist, who informed her about a clinical trial starting a few months later. In February 2020, Gayle became one of the first patients in Tennessee to participate in the clinical trial for TriClip. Despite the risks associated with being among the first patients to receive TriClip, the decision to undergo the procedure was almost instinctive for Gayle. She understood that the recovery and risks of open-heart surgery were far greater, leading her to opt for the smaller risks associated with the minimally invasive TriClip procedure.

After just one night in the hospital following the procedure, Gayle's life transformed. She immediately regained her energy and was able to cook breakfast for her family, who had come to town to care for her. Now, at 80, Gayle is back to hiking around the world and visiting her daughter and granddaughter in Santa Fe—activities she never imagined she would continue before the TriClip device.

Gayle's experience is just one of many illustrating how the TriClip device can significantly enhance patients' quality of life. She embodies the benefits TriClip offers to patients with tricuspid valve regurgitation: a renewed chance to enjoy daily activities without the complications, risks, and lengthy recovery associated with open-heart surgery.

A crucial element in the effective implementation of innovative treatments like TriClip is the healthcare team's role in guiding patient care through informed and shared decision-making. Heart Valve Voice US encourages CMS to adopt an evaluation process that leverages the expertise of specialized Heart Teams to provide comprehensive, patient-centered care, whether in-person or via telehealth. By streamlining these assessments, we can enhance care coordination and ensure equitable access to these breakthrough therapies for patients in diverse geographic areas.

Moreover, this approach will not only improve patient outcomes but also promote fairness in access to life-changing treatments. We urge CMS to consider the insights of patient advocates and medical experts when developing a regulatory framework that ensures equitable access based on geographic location while prioritizing safety in these procedures. Given that the needs of our community members vary significantly by location, CMS has a unique opportunity to uphold safety standards while addressing the diverse needs of patients nationwide.

We also want to emphasize the importance of including TriClip in the Transitional Coverage of Emerging Technology (TCET) Pilot. TriClip has proven to dramatically benefit patients

across the country like Gayle, and participation in the TCET Pilot allows many more patients to experience these benefits, ultimately leading to better health outcomes and more informed future coverage decisions.

Heart Valve Voice US strongly recommends that CMS adopt a comprehensive coverage policy for TriClip that prioritizes patients' needs while reflecting advancements in tricuspid valve treatment. For patients like Gayle, the TriClip device represents a new chance to live life to its fullest. CMS has the opportunity to enable thousands more patients to access this life-changing treatment.

Thank you for considering our perspective on this important matter. We look forward to continued dialogue and collaboration on policies that improve outcomes for Medicare beneficiaries with tricuspid regurgitation.

Sincerely,
Berkeley Barnett
Heart Valve Voice US
Director, Policy & Advocacy