



July 17, 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 group dedicated to enhancing the lives of individuals affected by heart valve disease, we appreciate the opportunity to comment on the NCD Tracking Sheet regarding Transcatheter Tricuspid Valve Replacement (TTVR). As an organization deeply rooted in patient-centered advocacy, HVV-US has a unique perspective to share regarding patients' lived experience with heart valve disease and the promise that breakthrough technologies provide. Recent advancements in transcatheter tricuspid therapies, such as the approval earlier this year of the breakthrough EVOQUE tricuspid replacement system, offer potential for patients who otherwise would not be able to address their valvular disease without more invasive options. With that in mind, HVV-US is hopeful that CMS will provide timely and adequate coverage for these new devices.

As you know, for patients grappling with tricuspid regurgitation, the availability of treatment options has historically been limited. In recent years, the landscape of transcatheter valve procedures has evolved significantly, with robust clinical experience and the establishment of multidisciplinary Heart Teams, necessitating policies that reflect these advancements. As Medicare considers a national coverage policy for TTVR, we believe it is imperative that CMS strike a balance between rigorous safeguards and expeditious patient access.

Drawing from past coverage policies, including those for TAVR and M-TEER, flexibility *in coverage criteria is essential* to prevent unintended barriers to care. Patients need inclusive coverage requirements that are sensitive to their diverse needs and that avoid unnecessary burdens and delays.

For HVV-US, the focus must include the lived patient experience with heart valve disease. One poignant example of the impact of timely intervention is the story of Mary, a member of our community who bravely navigated the challenges of tricuspid regurgitation.

In 2019, Mary was in hospice care, suffering from tricuspid regurgitation. Due to other health issues, she was unable to undergo open heart surgery to address her condition. She spent two years in and out of the hospital, knowing her tricuspid valve was failing. Her legs and feet were so swollen she couldn't lift her feet to walk, and she could only move from her bed to the couch to the bathroom. She couldn't comfortably lift her head, speak, or even breathe—her quality of life was severely diminished.

After two years of enduring tricuspid regurgitation, Mary felt she was reaching a breaking point and began preparing her critical documents and funeral plans; at her next follow-up

appointment, she asked her cardiologist what it would feel like to die. Shortly thereafter, she received a call informing her that she had qualified for a clinical trial surgery for the TTVR. Mary says she immediately began to feel hopeful.

Two months later, on January 11th, Mary woke up from her surgery and remembers laughing for the first time in over two years—it no longer physically hurt her body. By that afternoon, she was able to pick up her feet as she walked through the hospital halls and wasn't out of breath. She had a renewed sense of purpose and will to live.

Mary's journey illustrates the transformative potential of TTVR. Following the intervention with the EVOQUE system, she shared how her quality of life dramatically improved—a profound testament to the life-changing impact of innovative medical advancements.

Likewise, a critical component in the shared decision-making process of heart valve disease treatment is the clinician's role in evaluating and guiding patient care. HVV-US urges CMS to consider a streamlined evaluation process that leverages the expertise of Heart Team members to ensure comprehensive and patient-centered assessments. This approach not only enhances care coordination but also promotes equitable access to TTVR across diverse geographic settings.

Finally, the experience of the sites and operators is paramount in achieving optimal outcomes for patients. Input from stakeholders, including patient advocates and medical experts, is essential in establishing criteria that prioritize safety while ensuring equitable access based on geographic location. We urge CMS to prioritize policies that acknowledge the expertise and perspectives of these stakeholders. By incorporating their insights into regulatory frameworks, CMS can foster a healthcare environment that not only meets rigorous safety standards but also addresses the diverse needs of patients across the country.

In closing, Heart Valve Voice US urges CMS to adopt a coverage policy for TTVR that prioritizes patient needs while reflecting advancements in transcatheter valve technology. By fostering collaboration and patient-centered care through the Heart Team model, we can ensure that individuals suffering from tricuspid regurgitation, like Mary, receive timely access to transformative treatments like the EVOQUE system.

Thank you for considering our perspective on this critical matter. We look forward to continuing our dialogue and collaborating towards policies that improve outcomes for Medicare beneficiaries with tricuspid regurgitation.

Sincerely,

Berkeley Barnett
Heart Valve Voice US
Director, Policy & Advocacy