



July 19, 2024

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

Dear Administrator Brooks-LaSure,

As members of the Heart Valve Disease Policy Task Force, a national group of 30 leaders including clinician and patient advocates, we appreciate the opportunity to comment on the NCD Tracking Sheet regarding the Transcatheter Tricuspid Valve Replacement (TTVR) and want to emphasize the critical importance of establishing a comprehensive Medicare coverage policy that includes all FDA-approved minimally invasive transcatheter devices to improve quality of life and functional status in patients with symptomatic severe tricuspid regurgitation (TR) despite optimal medical therapy. Such a policy is not only pivotal in addressing the unmet needs of Medicare beneficiaries suffering from tricuspid regurgitation but also in facilitating timely access to innovative and life-saving technologies.

Importance of Establishing a Comprehensive Coverage Policy

Recent advancements, notably the FDA approvals of two transcatheter tricuspid therapies two months apart earlier this year, including the [EVOQUE Tricuspid Valve Replacement System](#), mark significant progress in the field. These innovations promise substantial improvements in patient outcomes, as evidenced by patient-reported outcomes from clinical trials. For instance, [53% of patients](#) treated with EVOQUE expressed a desire to regain independence in self-care post-intervention, highlighting the transformative potential of these technologies in enhancing quality of life. Coverage policies for these technologies would ensure that a broader range of patients have access to these life-changing treatments, thereby improving overall public health and reducing long-term healthcare costs associated with untreated or poorly managed tricuspid valve disease.

Role of Evolution and Previous Coverage Policies in Determining New Policy

The landscape of transcatheter valve procedures has evolved considerably over the past decade, characterized by deeper clinical experience and the establishment of expert Heart Teams. It is imperative that Medicare coverage policy for minimally invasive transcatheter devices in the treatment of TR reflects this evolution, ensuring that patients have access to these advancements without unnecessary delay or undue restrictions.

In formulating this policy, we urge CMS to act as swiftly as possible to incorporate lessons learned from previous coverage policies such as those for TAVR and M-TEER, as well as insights gained during the COVID-19 public health emergency. These insights underscore the need for balanced coverage policies that prioritize patient access while maintaining rigorous standards for safety and efficacy. For example, the temporary flexibilities introduced during the COVID-19 public health emergency, such as waiving face-to-face evaluation requirements and relaxing provider volume requirements, demonstrated that patient outcomes for TAVR procedures remained excellent even under these more flexible criteria. Additionally, the M-TEER determination includes use of interventions in patients with either functional or degenerative mitral regurgitation, with slightly different coverage requirements for each. These examples highlight how adaptable policies can effectively maintain high standards of care while expanding access to critical treatments, particularly in rural and underserved areas.

Patient-Centered Care in Coverage Determination

Furthermore, we emphasize the importance of patient-centered care in the coverage determination process. Requirements for pre-intervention evaluations should be streamlined to minimize burden on patients, avoiding unnecessary barriers that could hinder access to care. A single evaluation by a qualified member of the Heart Team, whether conducted in-person or via telehealth, should suffice to assess procedural suitability and ensure comprehensive patient evaluation. We also request that CMS refrain from layering on any required shared clinical decision-making (SCDM) requirements to this coverage determination, as we requested on TAVR. The use of SCDM as a condition of coverage creates confusion, and in effect, serves as a form of utilization management.

We understand that CMS will look to the specialty society consensus clinical treatment guidelines as the Medicare coverage determination process advances. While we support the structural heart team approach overall, we hope that as CMS crafts coverage requirements, it also considers the needs of patients with closer proximity to smaller and rural hospitals.

Considerations regarding the experience of medical providers and equitable geographic access must be carefully weighed to safeguard patient safety and ensure consistently high-quality care across diverse healthcare settings. Ensuring health equity is critical; thus, policies must incorporate the needs of underserved populations, including those in rural or economically disadvantaged areas, to prevent disparities in access to these advanced treatments. By addressing these inequities, we can ensure that all patients, regardless of their socioeconomic status or geographic location, can benefit from these medical advancements.

In conclusion, we strongly advocate for an inclusive and forward-thinking coverage policy that prioritizes patient access, integrates lessons from past experiences, and upholds the principles of patient-centered care to minimally invasive transcatheter valve devices. We appreciate the opportunity to provide input on this critical matter and look forward to continuing our collaboration with CMS to advance patient-centered policies.

Thank you for your attention to this important issue.

Sincerely,

Alliance for Patient Access
Caregiver Action Network
Conquering CHD
HealthyWomen
Heart Valve Voice US
Hypertrophic Cardiomyopathy Association
Men's Health Network
The Mended Hearts, Inc.
National Minority Quality Forum
Partnership to Advance Cardiovascular Health
RetireSafe