HEART VALVE DISEASE POLICY TASK FORCE

November 1, 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 advocacy organizations, we appreciate the opportunity to respond to the CMS NCD Tracking Sheet regarding Tricuspid Valve Transcatheter Edge-to-Edge Repair (T-TEER), also known as the TriClip G4 System. Expanding Medicare coverage to include all FDA-approved minimally invasive transcatheter devices is essential for improving outcomes for patients suffering from symptomatic tricuspid regurgitation (TR).

Currently, over 1.6 million Americans live with moderate or severe TR. Those with TR face debilitating symptoms such as severe fatigue, breathlessness, and complications such as enlarged liver, kidney failure and fluid accumulation in the abdomen, legs, ankles, or feet. Traditional treatment options, which mainly consist of medical therapies and invasive open-heart surgery, often fail to significantly enhance long-term survival. The mortality risk associated with untreated moderate and severe TR is stark – with mortality rates rising by 17% and 34% respectively. This highlights the pressing need for safer and more effective treatment alternatives. Transcatheter therapies, such as the FDA-approved TriClip G4 System, offer a promising, less invasive option that can significantly improve a patient's quality of life.

Medicare coverage policy for TR devices should reflect the advancements in medicine that continue to provide hope and options for patients. Importantly, evidence from recent clinical trials underscores the effectiveness of these technologies. For instance, 30 days after the TriClip procedure, 87% of patients experienced TR reduction to moderate or less, a stark contrast to the less than 5% of those treated with medication alone. Additionally, hospitalization rates decreased by 75% within three years post-procedure. Expanding Medicare coverage policies for these advanced technologies would not only enhance patient health outcomes but also reduce long-term healthcare costs associated with untreated TR.

We believe it is CMS' intent to create a policy that applies broadly to T-TEER devices and isn't limited to specific devices. Therefore, we urge CMS to adopt a "coverage to label" policy for FDA-approved devices. This approach will ensure that patients have continued access to new therapies as they become available. This flexibility is crucial, as future devices may have different indications. A broader coverage policy enables physicians to choose the best treatment options for their patients, particularly given the unique needs of those with TR.

We also want to emphasize the importance of T-TEER being included in the Transitional Coverage of Emerging Technology (TCET) Pilot. The concept of this pilot program could prove to be invaluable as it should allow patients timely access to innovative therapies while collecting essential data on their safety and effectiveness. By participating in the TCET Pilot, T-TEER could potentially help patients benefit from cutting-edge treatments, ultimately leading to better health outcomes and more informed coverage decisions in the future, but only if the process is as timely and efficient as intended.

Additionally, we must prioritize health equity in this coverage determination process. It is crucial to consider the unique challenges faced by underserved populations, especially those in rural and economically disadvantaged areas. Such communities often experience significant barriers to accessing advanced medical treatments, resulting in poorer health outcomes. This is where coverage requirements should allow for smaller and rural hospitals to participate from the beginning, without unnecessarily high procedural volume requirements. Ensuring equitable access to care must be a central focus of any new policy.

To achieve these goals, we hope that CMS streamlines pre-intervention evaluations to minimize burdens on patients. A single assessment by a qualified Heart Team member, whether conducted in-person or via telehealth, should suffice to determine procedural suitability. Additionally, we advocate that any hospital site requirements should take into account both patient outcomes and patient access.

In conclusion, we strongly advocate for a comprehensive and forward-thinking Medicare coverage policy that prioritizes patient access and patient centered care. By addressing health equity and recognizing the value of the TCET Pilot, we can help ensure that more patients potentially benefit from these minimally invasive treatments in an equitable and timely manner. We appreciate your attention to this critical issue and look forward to collaborating with CMS to develop policies that advance patient care.

Thank you for your consideration.

Sincerely,

The Heart Valve Disease Policy Task Force

Alliance for Patient Access
Association of Black Cardiologists
Caregiver Action Network
HealthyWomen
Heart Valve Voice US
Hypertrophic Cardiomyopathy Association
Men's Health Network
The Mended Hearts, Inc.
National Hispanic Health Foundation
National Minority Quality Forum
Partnership to Advance Cardiovascular Health
Preventive Cardiovascular Nurses Association
WomenHeart: The National Coalition for Women with Heart Disease