



January 17, 2025

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 proposed decision memo for national coverage for Transcatheter Tricuspid Valve Replacement (TTVR). In particular, we wish 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.

We applaud CMS's decision to move forward using Coverage with Evidence Development (CED), which facilitates patient access and in practice means patients should not have to wait for extended periods to benefit from medical advancements, particularly for conditions like tricuspid regurgitation, with limited treatment options. Existing and infrequently utilized treatments, such as surgery, carry high risks for older or medically complex patients. The proposed CED policy allows emerging minimally invasive technologies, such as TTVR, to be made available while additional data is collected, addressing unmet needs and gaps in care for vulnerable populations. This greatly improves patients' quality of life, by alleviating symptoms and increasing mobility and activity, allowing them to have much quicker recovery compared to open-heart surgery.

We also appreciate CMS recognizing that 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. The HVD Policy Task Force supports CMS's 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.

While it is important for patients to have the proper Heart Team, such teams should not be unduly burdened by size restrictions. This is especially crucial for those patients living in rural or economically disadvantaged areas in order to prevent access disparities to advanced treatments.

Furthermore, the Task Force greatly values CMS's emphasis on shared decision-making. Empowering patients to work closely with Heart Teams experienced in the management of tricuspid regurgitation fosters informed and patient-centered care. This approach respects individual preferences and ensures that treatment decisions align with patients' goals and priorities acknowledging that there is not a "one-size-fits-all" approach to care and treatment. By emphasizing trust in shared decision making, we can ensure equitable access, enabling all patients, regardless of socioeconomic status or geographic location, to receive the care they need.

However, the Task Force expresses concern that as proposed, the NCD does not establish coverage to all FDA labels and is instead tied to an existing TTVR technology. By establishing coverage based on a singular FDA label, the NCD could inadvertently limit future access to FDA approved indications for patients who could benefit from these therapies. The HVD Policy Task Force recommends revising the NCD to incorporate broader indications, including coverage to all labels, to allow for the expansion of indications for TTVR and enable more patients to receive coverage.

We also ask that CMS ensure that Medicare Advantage remain compliant with this NCD. Compliance with the NCD by Medicare Advantage plans assures that all Medicare beneficiaries, regardless of whether they are enrolled in Medicare or a Medicare Advantage plan, have equitable access to the same innovative and life-saving treatments. Without such enforcement, there is a risk of variability in coverage, which could lead to disparities in patient care. Non-compliance by Medicare Advantage plans could result in denials, delays, or additional administrative hurdles for beneficiaries seeking treatments covered under the NCD. By mandating compliance, CMS can safeguard patients from unnecessary obstacles that could impact their timely access to care and overall health outcomes, helping protect more vulnerable populations.

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 transcatheter valve devices. 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
HealthyWomen
Heart Valve Voice U.S.
Hypertrophic Cardiomyopathy Association (HCMA)
Men's Health Network
National Hispanic Health Foundation
Partnership to Advance Cardiovascular Health
Preventive Cardiovascular Nurses Association
RetireSafe
WomenHeart: The National Coalition for Women with Heart Disease