Association of Black Cardiologists, Inc.
Saving the Hearts and Minds of a Diverse America

January 16, 2025

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

Re: Public Comment on National Coverage Determination (NCD) for Transcatheter Tricuspid Valve Replacement (TTVR)

Dear Administrator Brooks-LaSure,

On behalf of the Association of Black Cardiologists (ABC), we are grateful for the opportunity to comment on CMS's ongoing analysis of coverage for Transcatheter Tricuspid Valve Replacement (TTVR). This technology represents a significant advancement in the treatment of tricuspid regurgitation (TR), a condition that causes debilitating symptoms and life-threatening complications for many Medicare beneficiaries, particularly those in underserved communities.

About the Association of Black Cardiologists

Founded in 1974, the Association of Black Cardiologists (ABC) is a nonprofit organization with a global membership of over 2,000, including health professionals, community health advocates, and institutional members. ABC's mission is to promote the prevention and treatment of cardiovascular disease, including stroke, in Black populations and other minority groups, striving for health equity through the elimination of disparities. ABC's inclusive membership welcomes all who align with its mission and vision. Through advocacy, education, research, and partnerships, ABC advances cardiovascular health and improves outcomes in communities nationwide. Learn more at www.abcardio.org.

Access for Underserved Communities

We urge CMS to establish a comprehensive Medicare coverage policy that ensures equal access to TTVR for all patients, especially those in underserved communities. For many individuals, particularly in rural or economically disadvantaged areas, TTVR is not merely an option but their only viable treatment for TR. Without access to this technology, these patients face outcomes of higher mortality, as there are no alternative interventions available.

We strongly believe that the **standard of care is getting the care you need in the community you live in.** Ensuring patients can receive treatment close to home reduces barriers related to travel, costs, and follow-up care, thereby improving health equity and outcomes.

Avoiding Unintended Consequences

We also urge CMS to consider how overly restrictive coverage requirements may unintentionally exacerbate gaps in care. If policies impose excessive procedural volume requirements, demand multi-provider evaluations, or limit the availability of TTVR to select centers, they may inadvertently exclude patients who are most in need of the procedure. While these may be seen as unintended consequences of the process,

it is imperative to recognize and address systemic barriers that these policies may create as they may result in preventable suffering and inequitable care.

Policy Recommendations for Equity and Access

1. **Streamlined Evaluation Requirements:** Allow evaluations to be conducted by a single Heart Team member, either in person or via telehealth, to reduce provider burden, especially for those in rural or underserved areas.

2. **Remove Arbitrary Volume Thresholds:** Evidence shows that outcomes for TTVR procedures remain excellent in both high- and low-volume centers.[1] Volume requirements should not impede the opening of new sites or the continued operation of centers serving disadvantaged populations. Retaining these onerous requirements restricts access to care, risks more TTVR and TAVR Centers shutting their doors, prevents the opening of new ones, and drives differences in treatment outcomes, as "patient proximity to hospitals impacts facility choice even when reported health outcomes differ significantly."

3. **Ensure Coverage Without Delay:** Swift adoption of an inclusive Medicare coverage determination for TTVR is essential. Lessons learned from prior policies for TAVR and other transcatheter interventions demonstrate that flexibility and patient-centered approaches promote equitable access while maintaining high standards of care.

Addressing Gaps in Health Care Services

Historical inequities in the diagnosis and treatment of valvular heart disease persist, particularly among racial and ethnic minorities.[2] TTVR coverage must explicitly address these gaps by prioritizing resources for minority-serving hospitals, offering payment incentives for underserved patient populations, and increasing awareness about TR and treatment options within these communities.

Conclusion

CMS has a unique opportunity to ensure that all Medicare beneficiaries suffering from TR have timely access to the life-saving TTVR technology. By adopting policies that prioritize access, minimize barriers, and reflect the needs of underserved communities, CMS can affirm its commitment to patient-centered care.

Thank you for considering these recommendations. We look forward to working with CMS to advance policies that improve outcomes for all patients.

Sincerely,

Anthony M. Fletcher, MD, FACC, FSCAI
President
Association of Black Cardiologists

1 R.T. Hahn et. al., Transcatheter Valve Replacement in Severe Tricuspid Regurgitation, The New England Journal of Medicine, p. 24 of the Supplemental Index, October 2024, *available at* https://www.nejm.org/doi/full/10.1056/NEJMoa2401918 . &

2 Lamprea-Montealegre JA, Oyetunji S, Bagur R, Otto CM. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9. J Am Coll Cardiol. 2021;78(24):2493-2504.