HEART VALVE DISEASE POLICY TASK FORCE

January 13, 2026

Administrator Mehmet Oz
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Oz,

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 National Coverage Analysis (NCA) for Transcatheter Aortic Valve Replacement (TAVR). We urge CMS to modernize the TAVR NCD to reflect the robust and mature evidence base, evolving clinical practice, and the critical need to ensure timely, equitable access for Medicare beneficiaries with aortic stenosis (AS), a life-threatening condition.

The current TAVR NCD must be updated to allow timely patient access to new and evolving FDA-approved indications, including the treatment of select patients with asymptomatic AS. Emerging clinical evidence and ongoing trials increasingly demonstrate that earlier intervention in appropriately selected asymptomatic patients may prevent irreversible cardiac damage, reduce downstream morbidity, and improve long-term outcomes.[1]

Coverage policy that relies solely on symptom status risks delaying care until disease progression results in poorer outcomes and increased healthcare utilization. Medicare beneficiaries should not be required to wait for clinical deterioration when earlier, evidence-based intervention may preserve quality of life and improve survival. Aligning coverage with contemporary evidence would ensure patients can access advances in early diagnosis and treatment without unnecessary delay.

In addition to expanding indications, we also encourage CMS to remove outdated and burdensome NCD requirements that create unnecessary barriers to patient care. TAVR is now established as the standard of care for patients with AS, yet certain structural and procedural requirements no longer reflect current practice patterns or patient needs. These outdated mandates, including rigid specifications on the number of operators during the procedure, may delay or prevent timely access to treatment for a condition that is both progressive and life-threatening. We believe the determination of how many qualified physicians are required for each TAVR procedure should be left to the discretion of the hospital based on clinical judgment,

[1] Philippe Généreux, Schwartz, A., J. Bradley Oldemeyer, Philippe Pibarot, Cohen, D. J., Blanke, P., Lindman, B. R., Vasilis Babaliaros, Fearon, W. F., Daniels, D. V., Chhatriwalla, A. K., Kavinsky, C., Gada, H., Shah, P., Szerlip, M., Dahle, T., Goel, K., O'Neill, W., Sheth, T., & Davidson, C. J. (2024). Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis. *New England Journal of Medicine*. https://doi.org/10.1056/nejmoa2405880

team experience, and patient needs. Streamlining these requirements would support more efficient care delivery while maintaining high standards for quality and patient safety.

The evidence also clearly demonstrates that TAVR is reasonable and necessary for the treatment of AS and no longer requires Coverage with Evidence Development (CED).[2] The continued application of CED requirements is inconsistent with the maturity of the evidence base and the widespread integration of TAVR into standard clinical practice. These administrative burdens restrict access to patient care, contribute to the closure of existing TAVR Centers, discourage the establishment of new centers, and exacerbate disparities in treatment outcomes. Research shows that patient proximity to hospitals significantly influences where care is received, even when reported health outcomes differ across facilities.[3] Sunsetting CED would better align Medicare policy with current science and clinical experience while reducing unnecessary barriers for both providers and patients.

Health equity and geographic access must remain central considerations in any updates to the TAVR NCD. Hospital and operator volume requirements, while originally intended to protect patient outcomes, can pose significant barriers for hospitals serving under-resourced, rural, or socioeconomically disadvantaged communities. These policies may inadvertently contribute to inequitable geographic distribution of TAVR services, leading to longer travel distances, increased wait times, and lower utilization rates among vulnerable populations.[4]

Evidence shows that access to TAVR becomes more equitable as the number of hospitals offering the procedure increases. From 2016 to 2019, a 30 percent increase in the number of TAVR hospitals coincided with a 31 percent decrease in procedure access inequality.[5] Given that AS remains significantly undertreated, we believe access to care can be improved in part by appropriately expanding the number of centers able to offer TAVR.

Like many therapies in healthcare, the availability of TAVR should be guided by community and patient need rather than arbitrary hospital or operator volume thresholds. At a minimum, programs already providing structural heart care should have the flexibility to offer TAVR where clinically appropriate. Over time this may reasonably include the addition of several hundred centers over time as patient demand and community need warrant, ensuring that Medicare beneficiaries can receive timely care close to home.

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[2] Carroll, J. D., Mack, M. J., Vemulapalli, S., Herrmann, H. C., Gleason, T. G., Hanzel, G., … Bavaria, J. E. (2020). STS-ACC TVT Registry of transcatheter aortic valve replacement. *Journal of the American College of Cardiology, 76*(21), 2492–2516. https://doi.org/10.1016/j.jacc.2020.09.595

[3] Alliance for Aging Research. Comments submitted to CMS Administrator Seema Verma on Proposed decision on Medicare's National Coverage Decision (NCD) for transcatheter aortic valve replacement (TAVR) (CAG-00430R). April 2019. https://www.agingresearch.org/wp-content/uploads/2018/07/CMS-Proposed-TAVR-Decision-Response-4-25-19.pdf

[4] Damluji, A. A., Fabbro, M., Epstein, R. A., Rayer, S., Wang, Y., Moscucci, M., Cohen, M. G., Carroll, J. M., Messenger, J. C., Resar, J. R., Cohen, D., Sherwood, M. W., O'Connor, C. M., & Batchelor, W. (2020). *Transcatheter Aortic Valve Replacement in Low-Population Density Areas*. *13*(8). https://doi.org/10.1161/circoutcomes.119.006245

[5] Bergman, A., David, G., Nathan, A., Giri, J., Ryan, M., Chikermane, S., Thompson, C., Clancy, S., & Gunnarsson, C. (2024). Measuring hospital inpatient Procedure Access Inequality in the United States. *Health Affairs Scholar*, *2*(11). https://doi.org/10.1093/haschl/qxae142

In conclusion, we strongly encourage CMS to modernize the TAVR NCD by expanding indications, sunsetting CED requirements, and removing outdated barriers that unnecessarily limit patient access. An updated, evidence-based coverage policy will better reflect current clinical practice, improve health equity, and ensure that Medicare beneficiaries with aortic stenosis can access timely, life-saving care regardless of geography or socioeconomic status.

We appreciate the opportunity to provide these comments and look forward to continued collaboration with CMS to advance patient-centered, equitable coverage policies.

Thank you for your consideration of this important issue.

Sincerely,

The Heart Valve Disease Policy Task Force

Alliance for Aging Research

Alliance for Patient Access

Caregiver Action Network

Heart Valve Voice US

Hypertrophic Cardiomyopathy Association

Men's Health Network

The Mended Hearts, Inc.

National Minority Quality Forum

Partnership to Advance Cardiovascular Health

Preventive Cardiovascular Nurses Association

WomenHeart: The National Coalition for Women with Heart Disease