Heart Valve
Voice US

January 14, 2026

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

Dear Administrator Oz,

On behalf of Heart Valve Voice US (HVV-US), a national non-profit patient advocacy organization dedicated to enhancing the lives of individuals affected by heart valve disease, we appreciate the opportunity to comment on the National Coverage Analysis (NCA) for Transcatheter Aortic Valve Replacement (TAVR). As a patient-centered organization, HVV-US brings a unique perspective informed by patients' lived experiences with heart valve disease and the promise that breakthrough technologies provide. We respectfully urge CMS to update the TAVR National Coverage Determination (NCD) to align with the strength of current clinical evidence, contemporary standards of care, and the urgent need to ensure Medicare beneficiaries with aortic stenosis (AS) have fair and timely access to treatment for this life-threatening condition.

The need for change is reflected in the experience of one of our advocates, Kim, who was diagnosed at birth with Tetralogy of Fallot, a congenital heart condition. She underwent her first surgery at just three weeks old, when a shunt was implanted to help her survive until she could undergo open-heart surgery. At age five, Kim had open-heart surgery that corrected her Tetralogy of Fallot symptoms.

During her junior year of high school, a routine checkup revealed an abnormal echocardiogram. Physicians determined that her heart valve was leaking and required repair, leading to a second open-heart surgery in which a human valve was implanted.

Decades later, in 2019, Kim began experiencing symptoms again, including shortness of breath and significant fluid retention in her legs. After years without regular cardiology care, she decided to see a cardiologist. At the time, she was told her valve was still functioning but leaking and would eventually need to be replaced.

Learning about TAVR changed Kim's perspective and ultimately her life. Unlike open-heart surgery, TAVR offered a less invasive option, giving her and her doctors the confidence to move forward with treatment. By the time she decided to proceed, her condition had significantly worsened and she could barely breathe. Knowing she could not wait any longer, Kim underwent TAVR in March 2023.

Kim's experience illustrates why TAVR coverage should extend to appropriately selected patients with initially asymptomatic AS. Under current policy, patients are often required to wait until symptoms significantly impair quality of life before qualifying for intervention. This approach allows disease progression that could be mitigated through earlier, evidence-based treatment and places unnecessary physical and emotional burdens on patients. Patients should not be required to wait for an initially asymptomatic condition to worsen into a symptomatic one, or for their quality of life to decline, before qualifying for intervention.

When Kim learned about TAVR, she finally had a viable alternative. The results of her procedure were immediate and profound. Her excess fluid resolved, color returned to her face, and she felt “uplifted and light.” Within a week, Kim was able to travel internationally and fully resume her active life. Her outcome, along with those of hundreds of other patients, demonstrates that TAVR is a proven and effective therapy and no longer warrants continued Coverage with Evidence Development (CED). Maintaining CED imposes administrative burdens that restrict patient access, limit provider participation, and slow the expansion of care where it is needed most.

We also encourage CMS to remove outdated procedural requirements within the NCD, including rigid specifications regarding staffing and operator roles. These mandates reflect early-stage implementation rather than modern, team-based clinical practice and may unnecessarily limit where TAVR can be offered and who can receive it. Decisions regarding procedural staffing should be left to hospitals and qualified heart teams, whose clinical judgment and experience are best suited to meet individual patient needs while maintaining high standards of safety and quality. While Kim received care from an experienced heart team at a Center of Excellence in Georgia, many patients do not live near hospitals that can meet the NCD’s prescriptive requirements, creating inequitable access to care.

Patients should not have to wait for their health to deteriorate before accessing a life-saving therapy. By expanding indications, sunsetting CED, and removing outdated barriers, CMS can align the TAVR NCD with current evidence and ensure Medicare beneficiaries receive timely, high-quality care regardless of where they live.

In conclusion, we strongly encourage CMS to modernize the TAVR NCD by expanding indications, sunsetting CED requirements, and removing outdated barriers to access. As Kim’s story illustrates, timely, minimally invasive treatment allows patients with heart valve disease to continue living robust, full lives. Aligning coverage with current evidence will promote equity and ensure access to life-saving care for Medicare beneficiaries nationwide.

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,

Berkeley Barnett
Director of Policy & Advocacy
Heart Valve Voice US