July 15, 2026

Joseph Hutter, MD
Lead Medical Advisor

Sarah Fulton, MHS
Lead Analyst
Center Medicare & Medicaid Services

Re: *Proposed Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R2, NCA-CAL-321)*

Dear Dr. Hutter and Ms Fulton:

The 20 undersigned patient advocacy, health provider, and family caregiver organizations applaud and thank the Centers for Medicare & Medicaid Services (CMS) for its proposed National Coverage Determination (NCD) update for Transcatheter Aortic Valve Replacement (TAVR) and this opportunity to comment. The proposed updates to Medicare's national TAVR coverage policy represent a transformative milestone for heart-valve disease patients and their families. The TAVR procedure is often preferred by patients with severe aortic stenosis (AS) because it avoids open-heart surgery and allows quicker treatment and recovery. It also reduces first-year health care costs by about $10,000 per patient for Medicare and taxpayers.

By lifting the 14-year Coverage with Evidence Development (CED) requirement, CMS is formally recognizing that TAVR is reasonable and necessary for the treatment of severe, symptomatic AS. In addition, updates to the TAVR coverage criteria related to pre-procedural patient assessment, intraoperative requirements, and operator and hospital procedural volume requirements shift the focus to where it matters most: TAVR proficiency, data-driven quality, patient experience, and relevant operator expertise.

We urge CMS to finalize these pivotal changes to expand TAVR access, and ***build on this progress by extending the same national coverage approach—without CED—to Medicare patients with asymptomatic severe AS*. Such a decision would not only align with the CMS Administrator's goals to modernize and streamline Medicare utilization management, but it would also remove barriers to less invasive AS care for all beneficiaries, in all areas of the U.S.**

Additionally, once the TAVR NCD is finalized, we encourage CMS to reconsider use of CED in Medicare, because it interferes in the practice of medicine and impacts access to care for millions of beneficiaries annually.

Ending CED for Symptomatic Severe Aortic Stenosis (AS) Is Overdue

An estimated 2.5 million people over the age of 75 have AS, one of the most common types of heart valve disease. Left untreated, it can progress rapidly to severe AS, and once symptoms appear, 1 in 10 may die within five weeks.

When the FDA first approved TAVR in 2011, it was an important advancement for older adults with severe, symptomatic aortic stenosis who needed their valves replaced but were too ill or frail to withstand open-chest surgery. The American College of Cardiology and Society for Thoracic Surgeons sent a formal request to Medicare to initiate a TAVR NCD requiring CED, and co-led the introduction of the CMS-approved, TVT registry clinical study in 2012.

By 2017, TAVR became the clinical standard of care for most patients with symptomatic, severe AS, supported by robust randomized trial data and reflected in professional society guidelines soon thereafter. Despite this clear clinical consensus nearly 10 years ago, Medicare coverage for TAVR remained subject to CED, creating a growing disconnect between specialty clinical guidelines and CMS policy. CMS reconsidered the NCD in 2019, which expanded TAVR coverage to lower-risk patients but kept the CED and other outdated coverage requirements.

This incongruence is starkly reflected in patient access. In 2019, the CED registry reported that only 72,991 patients received TAVR. That may sound like a high level of access, but a 2017 article in the American Heart Association Journal, *Circulation: Cardiovascular Quality and Outcomes*, found that only 31% of U.S. patients potentially eligible for TAVR had been treated with the procedure.

Not surprisingly, TAVR access issues hit patients who live in underserved communities the hardest. Research on TAVR access inequalities from February 2026 found that areas with lower-than-expected TAVR utilization due to CED coverage restrictions are not just experiencing access gaps, but also significantly higher rates of death.

In another example, USC Schaeffer Center research finds that patients in rural areas are underrepresented at TAVR hospitals and can't access the procedure closer to home. Delayed care can cost patients both their money and their lives. Those treated more than ninety days after diagnosis face a 50 percent higher risk of death over three years and nearly $37,000 in additional health care costs compared to those treated promptly. And even at a TAVR hospital, CED's onerous requirements add an average of 59 days to the timeline between diagnosis and treatment.

There have now been more than 25 TAVR clinical trials and more than 1 million TAVR patients captured in the required registry, with results published in nearly 20,000 articles. CMS can confidently declare success in lifting the CED and other requirements, and we join the American public in supporting them. In May, the Alliance for Aging Research commissioned a poll of 1,000 U.S. adults on the potential impact of these changes. Overall, 77% of participants said they agree Medicare should cover TAVR "the same way that it covers open-heart surgery" and 67% said they would be more likely to support a political candidate who "supports requiring Medicare to broaden patient access to TAVR."

Emphasizing Proficiency, Data-Driven Quality, Patient Experience, and Relevant Operator Expertise

We also support the other updates in the proposed decision memo. These include:

- **Reducing patient burden:** shifting the heart team evaluation to using medical records plus one required in-person visit with a member of the heart team, which will provide immense relief to patients and their families;
- **Modernizing quality metrics:** judging hospitals on quality improvement instead of rigid yearly procedure counts, helping ensure that patient outcomes dictate success;

- **Putting patients at the center:** promoting shared decision-making and patient-centered treatment selection;
- **Expanding health access:** allowing single-operators where appropriate and prioritizing procedural proficiency over rigid structural volume requirements—including eliminating annual quotas for unrelated cardiac procedures—safeguarding quality while broadening hospital participation in historically underserved communities;
- **Requiring data sharing:** making CED clinical study data accessible to both CMS and the public to better inform research and future coverage policy; and
- **Future-proofing pathways:** utilizing Medicare Administrative Contractor (MAC) coverage discretion to accommodate future clinical indications creates a vital coverage framework without undergoing the lengthy NCD reopening process.

CMS Should Apply the Same Standards to Asymptomatic Severe AS

CMS should not impose CED for newer indications of TAVR, including use in asymptomatic patients, where the clinical evidence base is already clear and continuing to evolve through routine clinical practice. Research in the October 2024 *New England Journal of Medicine* study found that treating severe AS patients with TAVR *prior* to experiencing any symptoms lowered risk of death, stroke or unplanned hospitalization for cardiovascular outcomes compared with those who had routine clinical surveillance (also known as "watchful waiting").

The FDA approved TAVR to treat asymptomatic AS in May 2025, and patients have been facing inconsistent Medicare coverage as they wait for CMS to make its decision. **While we are supportive of inclusion of TAVR coverage for asymptomatic AS in the NCD, we oppose the application of CED and other conditional coverage requirements on this indication.** Thousands of published studies for prior TAVR indications demonstrate that layering restrictive coverage requirements on to the asymptomatic AS indication is more likely to delay access and create unnecessary barriers to care. CMS should provide clear and consistent national coverage rather than rely on CED mechanisms that are no longer justified.

We Encourage CMS to Reconsider Use of CED in Medicare

Once the TAVR NCD is finalized, we encourage CMS to reconsider use of CED in Medicare, because it interferes in the practice of medicine and impacts access to care for millions of beneficiaries annually. Since 2005, when Medicare created CED, CMS has applied it to more than 30 treatments and tests for certain cancers, sickle cell disease, and severe hearing loss (cochlear implants), among other conditions. And in April 2022, Medicare applied CED to an entire class of FDA-approved treatments for early Alzheimer's disease. This marked the first time Medicare extended CED beyond medical devices and diagnostics to restrict the on-label use of FDA-approved prescription drugs.

The CED restriction on Alzheimer's therapies has been more significant than the agency predicted. A May 11 article in *STAT News* found that "People on Medicare are not getting the recently approved Alzheimer's medications nearly as much as federal officials anticipated."

Older adults meet with their health care providers, often alongside family caregivers, to discuss the benefits and risks of treatment, according to their diagnosis and needs. Section 1801 of the Social

Security Act bars federal officials from interfering in the practice of medicine, which raises questions about CMS's authority to condition Medicare coverage on participation in a study. In a January 2021 advisory opinion, then-HHS General Counsel Robert Charrow found that CMS's use of CED was fundamentally inconsistent with the law and concluded that such restrictions were unlawful. Though that opinion has since been rescinded, its legal reasoning has not been refuted.

Conclusion

We thank CMS for this patient-centered proposal and urge the agency to finalize it, together with the changes requested above, without unnecessary delay. Please contact Candace DeMatteis, Policy Director at the Partnership to Fight Chronic Disease at candace.dematteis@fightchronicdisease.org; or Sue Peschin, President & CEO, Alliance for Aging Research at speschin@agingresearch.org, with any questions. We welcome the opportunity to serve as a resource to CMS as this policy is finalized.

Respectfully submitted,

Alliance for Aging Research
Alliance for Patient Access
ASCP - Age Friendly Pharmacists and Pharmacies
Association of Black Cardiologists
Caregiver Action Network
CaringKind, The Heart of Alzheimer's Caregiving
Global Alzheimer's Platform Foundation
Global Coalition on Aging
HealthHIV
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
National Alliance for Caregiving
National Association of Nutrition and Aging Services Programs (NANASP)
National Consumers League
National Grange
National Minority Quality Forum
Nevada Chronic Care Collaborative
Partnership to Fight Chronic Disease
RetireSafe
Voices of Alzheimer’s