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January 14, 2026

JoAnna Baldwin
Acting Director, Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CAG-00430R2

Re: Public Comment on Proposed National Coverage Determination for Transcatheter Aortic Valve Replacement, CAG-00430R2

Dear Ms. Baldwin:

The Alliance for Aging Research ("Alliance") applauds CMS for reconsidering the TAVR NCD, and we strongly urge the agency to 1) remove CED and other outdated coverage requirements and 2) expand national coverage to all FDA-approved uses for the treatment of symptomatic and asymptomatic aortic stenosis (AS). The Alliance is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care.

The CMS TAVR NCA is a pivotal opportunity for this Administration to balance a reduction in Medicare costs[1] with improved patient access to a preferred, less invasive treatment option—including shorter hospital stays and recovery times, better quality of life measures, and lower incidence of some major complications across all surgical risk levels.[2,3] The latest good news comes from the October 2024 results of the EARLY TAVR trial for those with clinically significant, asymptomatic severe AS, published in the *New England Journal of Medicine*[4], which found those who had TAVR had lower incidence of death, stroke, or unplanned hospitalization for cardiovascular outcomes compared with those who had routine clinical surveillance (i.e., "watchful waiting"). The FDA subsequently approved the use of TAVR in asymptomatic AS in May of 2025.

Unfortunately, the current TAVR NCD does not include Medicare coverage for the asymptomatic AS indication. This leaves beneficiaries with inconsistent coverage at the local level.

As CMS carefully considers the 14 years of extensive evidence on TAVR, we hope they confidently declare success by removing the CED and other coverage requirements from the NCD and expanding national coverage to all FDA-approved indications for AS treatment. 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.

TAVR has Been the Established Standard of Care Since 2017

An estimated 2.5 million people over the age of 75 have aortic stenosis, one of the most common types of heart valve disease.[5,6] Left untreated, it can progress rapidly and unpredictably to severe aortic stenosis, and it is estimated that 1 in 10 patients experiencing symptoms of severe aortic stenosis may die within five weeks.[7]

When the FDA first approved TAVR in 2011, it was an important advancement for older adults with severe aortic stenosis who needed an aortic valve 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.[8]

TAVR for patients with symptomatic, severe aortic stenosis became the clinical standard of care in 2017 for high-risk, inoperable, and increasingly, intermediate-risk patients, supported by robust randomized trial data and reflected in professional society guidelines soon thereafter.[9,10] Despite this clear clinical consensus nearly 10 years ago, Medicare coverage for TAVR has remained subject to CED, creating a growing disconnect between specialty clinical guidelines and CMS policy.

This incongruence is starkly reflected in patient access. In 2019 the TVT Registry reported that 72,991 patients received TAVR.[11] That sounds like a high level of access, but a 2017 article in the American Heart Association Journal, *Circulation: Cardiovascular Quality and Outcomes*, suggests otherwise. The analysis estimates that the number of U.S. patients with severe symptomatic aortic stenosis eligible for TAVR at high-risk is 111,205; intermediate risk is 34,991; and low risk 89,736—a total of 235,932 eligible patients. **Using those estimates, only 31% of those potentially eligible for TAVR have been treated with the procedure in the U.S.[12]**

The Financial Tug-of-War Between Specialist Societies, Major Medical Centers, and Smaller/Rural Hospitals

For nearly 14 years, Medicare patients with AS have been stuck in the middle of a professional sea change in heart valve disease among thoracic surgeons and interventional cardiologists, as well as between major medical centers and smaller, community-based/rural hospitals. Medicare coverage for TAVR is entrenched in both the CED registry-based study requirements and procedural volume coverage criteria that have an outsized financial benefit to large, well-resourced medical centers and the organizations that manage these data systems.

There are two major financial incentives at play here. First, the American College of Cardiologists Foundation—and to a lesser degree the Society for Thoracic Surgeons—makes tens millions of dollars annually[13] off its TVT and other registry products.[14] When the Alliance inquired, the TVT Registry charged a one-time set-up fee ($25,000) and an annual participation fee ($10,000) per facility, which today totals 860 participating hospitals. The companies that make TAVR valves also pay the societies for registry data on their own products. Smaller, community based and rural hospitals often lack the infrastructure or financial ability to participate in the registries, or meet minimum procedural volume requirements, and therefore are unable to offer TAVR, stopping patients from receiving the treatment, or, more commonly, funneling them back to larger hospital systems which stand to profit from their business.

It is important to note that TVT registry sponsors appoint the advisors that decide on the health outcomes information collected; own the registry data; control who can access the data; and determine what types of analyses may be conducted using the data. CMS currently has no direct access to the registry data and no enforcement authority over whether or how the agency's registry-related evidence questions are answered, let alone answered within a designated period. As a result, CEDs may drag out for a decade or more with no definitive end—leaving beneficiary access hanging in uncertainty.

Moreover, the TAVR Data Collection Form v3 form, available on the TVT Registry website[15], is onerous at 11 pages long and the registry has collected massive amounts of data on millions of patients, resulting in hundreds of published studies. The question is, what is the evidence threshold needed to end the TAVR CED? Specialty societies and many large hospitals argue in this NCA public comment that there is no threshold. That concerns us as patient advocates, and we hope CMS shares our concern.

The result is beneficiaries are left navigating a system that is shaped less by clinical need than by institutional resources, administrative compliance, and professional turf.

<u>14 Years of TAVR CED is Utilization Management Abuse</u>

NCD with CED is a markedly restrictive coverage requirement. It is important to note that the Agency's CED policy was not authorized by Congress—it was created and implemented by CMS starting in 2005 as a NCD requiring study participation. The CED "paradigm," as coined by CMS, was first outlined in a 2006 regulatory guidance, and updated in 2014.

Initially, CED was utilized to accelerate access to medical devices, which have fewer clinical trial requirements in comparison to drugs and biologics. As time passed, CMS expanded its use of CED to other therapeutic types and diagnostics. Under CED, the Agency denies Medicare coverage for an FDA-approved item or service except when it is provided to beneficiaries within a population-limited clinical study, such as a CMS-approved clinical trial or data registry. Beneficiaries who are ineligible under the strict CED requirements, cannot access the clinical study sites, or are reluctant to be required to enroll in a clinical study to receive access are left without coverage. Once CMS places a

treatment in CED, it is extraordinarily difficult for the coverage restriction to be lifted. An August 2022 systematic review of CED program history, published in The American Journal of Managed Care identified that, between 2005–2022, CMS issued a total of 27 NCDs requiring CED. Only four have been retired[16] by the Agency, which has taken an average of 8 years to do so.[17] Under its current paradigm, CMS has enabled 22 CEDs to continue in perpetuity, including several that have been ongoing for more than 15 years.[18]

Broadly, the Alliance is concerned about the implications that the continuation of a CED would have on Medicare beneficiaries' ability to access TAVR. CED limits beneficiaries' ability to obtain care outside narrowly defined parameters by requiring that beneficiaries participate in specific clinical trial registries and receive care at only designated setting by certain specialists. While the Medicare program is not supposed to consider cost when making coverage determinations, former HHS assistant secretary Dr. Richard Frank has characterized NCDs as "the most powerful coverage tool that Medicare has and have generally been reserved for Medicare services that are costly …". This quote serves as a peek behind the curtain of the fundamental flaw of CED: it uses the "need" for further evidence as a barrier to patient access.

This is especially true for beneficiaries in rural areas, who are unable to travel to study sites. Requiring beneficiaries to travel to designated study sites as a condition of coverage disproportionately harms rural communities by creating geographic and logistical barriers that many patients cannot realistically overcome. Rural beneficiaries often live hours from academic medical centers where CED studies are typically conducted, and long distances can be especially burdensome for older adults, people with disabilities, and those managing chronic or progressive conditions. These challenges are further compounded by limited access to reliable transportation, fewer local specialty providers, and higher out-of-pocket costs for travel and lodging. In 2019, a Morning Consult survey found that one in three rural adults and 36% of rural adults age 65+ find it difficult to access large urban-based hospitals.[19] These individuals reported that appointment availability, insurance coverage, travel distance and costs, and wait times are the top barriers to accessing large urban-based hospitals for treatment.

Legal Authority

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. It is against federal law for CMS to interfere with clinical care. Section 1801 of the Medicare law states, "Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."[20] Section 1801 was included in the law to offset the criticism made by opponents of the proposal that Federal legislation would give Federal officials the opportunity and the right to interfere in the diagnosis and treatment of the individual.[21]

As is substantially noted in the Alliance's 2023 report *Façade of Evidence,* CED is not mentioned in statute and was originally developed by CMS in a 2006 guidance.[22] Congress has not ratified CMS' CED powers, or authorized CMS to conduct research studies into the effectiveness of medications or medical devices. In fact, Robert Charrow, former HHS General Counsel, previously issued an HHS Office of General Counsel Advisory Opinion explaining that CMS' interpretation of its statutory authority to use CED as the basis for coverage of items and services is "unlawful [...]" because CMS's "broad reading of the term [support] is fundamentally inconsistent with" the legal definition of public health service support.[23]

Recommendations

Now, TAVR is being investigated for earlier intervention in moderate or even asymptomatic patients to determine if preventative treatment using TAVR can stop damage from progressing more broadly. Traditionally, these patients have been managed with a "watchful waiting" approach until symptoms develop—a technique that was used to avoid the risks and complications of a procedure before it was necessary to confront those risks. Now, growing evidence suggests that TAVR can be used as a tool to prevent heart damage before it can occur, allowing patients to experience better quality of life and long-term cardiac outcomes if the TAVR intervention is done earlier. Continuing to apply CED to established indications conflates emerging research needs with settled science, unnecessarily restricting access for beneficiaries who already meet long-standing clinical criteria. CMS should retire CED for prior indications.

Further, 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. Randomized controlled trials and long-term follow-up data demonstrate the safety and effectiveness of TAVR across a broad range of patient risk profiles, and clinical guidelines have already incorporated these findings into standard care pathways. Additional conditional coverage requirements would not meaningfully improve the evidence base but would instead delay access to appropriate treatment 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.

Lastly, CMS should avoid using gaps in evidence for patients with comorbid conditions as justification for coverage policies that further narrow access to TAVR for those with the greatest clinical need. Issuing a CED decision that adds new clinical study requirements, restrictive coverage conditions related to sites of care or specialist type, or burdensome data collection mandates, risks delaying or restricting access for patients with multiple or high-risk comorbidities. These populations are often underrepresented in studies but are among those most likely to rely on TAVR as a less invasive treatment option. The clinical evidence base already exists, and CED would only reduce the availability of these

treatments for patients who need them most. Rather than enabling study of these populations, CED risks shrinking and distorting the very data CMS seeks to obtain.

Conclusion

CMS should move forward with a full NCD for TAVR without the use of CED for any indication. The existing clinical trial data, real-world evidence, and incorporation of TAVR into clinical guidelines together support broad and consistent coverage, and continued reliance on CED is no longer appropriate or necessary. The Alliance appreciates CMS's consideration of these comments and stands ready to work with the agency as it evaluates this NCA. Please do not hesitate to contact Adina Lasser, Director of Public Policy and Government Relations, at alasser@agingresearch.org with any questions or requests for additional information.

Sincerely,

Susan Peschin, MHS
President and CEO
Alliance for Aging Research

Adina Lasser
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Alliance for Aging Research

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[23] Robert Charrow, Advisory Opinion 21-03 on Medicare Coverage with Evidence Development, U.S. Dep't of Health & Human Servs. at 2 (Jan. 14, 2021) (emphasis added) (rescinded). While this advisory opinion has since been withdrawn, Charrow's legal interpretation remains valid.