JenaValve Technology, Inc.
4 Cromwell
Irvine, California 92618

July 14, 2026

Via Overnight Courier

Sarah Fulton, MHS, Lead Analyst
Joseph Hutter, MD, MA, Lead Medical Officer
Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mailstop S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

Re: Proposed Decision Memorandum for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R2)

Dear Ms. Fulton and Dr. Hutter:

On behalf of JenaValve Technology, Inc. ("JenaValve"), I write to transmit the enclosed redline of the proposed revisions to the Appendix A Medicare NCD Manual language for transcatheter aortic valve replacement, prepared by Stuart Langbein of Hogan Lovells US LLP, counsel to JenaValve. JenaValve respectfully submits this redline for the agency's consideration as part of its comments on the proposed decision memorandum for NCA CAG-00430R2.

JenaValve is submitting its comment letter electronically through the CMS Medicare Coverage Database comment portal. The enclosed redline sets out the consolidated proposed revisions referenced in that letter, implementing JenaValve's Requests 1 through 4. We respectfully ask that this enclosure be associated with JenaValve's electronically submitted comment and included in the record for this reconsideration.

Thank you for your consideration of these materials and for the care the agency has brought to this reconsideration. Please do not hesitate to contact me with any questions or if additional copies would be helpful.

Respectfully submitted,

Courtney Darby
Head of Global Health Economics and Market Access
JenaValve Technology, Inc.

Enclosure: Redline of proposed revisions to the Appendix A Medicare NCD Manual language (CAG-00430R2)
cc: Stuart Langbein, Esq., Hogan Lovells US LLP

REVISION FOR AR COVERAGE VIA CED

20.32 - Transcatheter Aortic Valve Replacement (TAVR)

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A. General

Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

B. Nationally Covered Indications

TAVR is covered for severe aortic valve stenosis (or aortic stenosis (AS)) when furnished with a complete aortic valve and implantation system that has received Food and Drug Administration (FDA) premarket approval (PMA) for that system's FDA-approved indication, and the following conditions are met.

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1. Patient Criteria

TAVR is covered for the treatment of Medicare beneficiaries with:

a. Symptomatic severe AS under § 1862(a)(1)(A) of the Social Security Act (the Act).
b. Asymptomatic severe AS under coverage with evidence development (CED), § 1862(a)(1)(E) of the Act.

Provisions in B2 and B3 below apply to all TAVR procedures furnished under the NCD; provision B4 applies only to TAVR procedures furnished under CED.

2. Physician and Heart Team Criteria

Heart Team: The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary team of medical professionals with a specialized focus in cardiac care. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team:

a. Must include at least one cardiac surgeon and one interventional cardiologist experienced in the care and treatment of AS and each with clinical privileges at the hospital where the TAVR will be furnished; and
b. May include other physicians, advanced practice clinicians, and nurses, as well as research personnel and administrators.

Patient Evaluation: Suitability for surgical aortic valve replacement (SAVR), TAVR, close surveillance, and palliative care must be evaluated based on individual clinical, anatomical, and procedural characteristics, lifetime management considerations, and estimated patient life expectancy. These evaluations must be documented by a cardiac surgeon and by an interventional cardiologist of the heart team and made available to other heart team members, the patient, and other clinicians involved in the patient's care as appropriate, prior to the day of the procedure. Evaluations must include:

a. An initial evaluation by the heart team, which could be asynchronous using medical records to identify patient suitability for TAVR or other treatments; and
b. An independent, in person evaluation by a heart team TAVR operator. This cannot be satisfied through a virtual encounter.

TAVR Operator: A TAVR operator must be an interventional cardiologist or cardiac surgeon member of the heart team and:

a. Perform ≥ 20 total transcatheter cardiac valve (including aortic, mitral, tricuspid, or pulmonic valve) procedures, ≥ 15 of which must be TAVR, every year; or
b. Perform ≥ 40 such procedures, ≥ 30 of which must be TAVR, every two years.

Joint participation of two TAVR operators in a TAVR procedure is not required but may occur if determined appropriate by the heart team. If jointly performed, both must be TAVR operators from the heart team.

3. Hospital Criteria

TAVR procedures must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

a. On-site structural heart interventional cardiology and cardiac surgery programs.
b. A post-procedure intensive care unit with personnel experienced in managing patients who have undergone open-heart valve procedures.
c. A continuous quality improvement process that assesses procedural outcomes and makes necessary programmatic adjustments to assure patient safety.

4. CED Study Criteria

TAVR items and services are furnished for the treatment of asymptomatic severe AS with a complete aortic valve and implantation system that has received FDA PMA for that system's FDA-approved indication in the context of a CMS-approved CED study.
CED studies must meet requirements of sections B2 (Physician and Heart Team Criteria) and B3 (Hospital Criteria), have an active, contemporaneous comparator and address at least one of the following questions:

- Does TAVR, SAVR, or close surveillance until symptom onset better improve health outcomes? This is particularly relevant for patients with lower surgical risk, longer life expectancy, preserved left ventricular ejection fraction, and bicuspid aortic valves.
- What are the long-term valve re-intervention rates of TAVR vs SAVR and does having re-interventions impact health outcomes?
- Can longer term, risk-standardized, patient-centered health outcomes replace volume criteria for TAVR operators?

CMS-approved CED studies must adhere to the following scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI of CMS' Coverage with Evidence Development Guidance Document , published August 7, 2024 (the "CED Guidance Document").

1. Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.
2. Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.
3. Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.
4. Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.
5. Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.
6. Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors.
7. Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically-relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.
8. Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.
9. Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.
10. Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.
12. Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.
13. Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.
14. Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with incomplete results).
15. Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.
16. Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.
17. Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely-debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

The principal investigator must submit the complete study protocol including the statistical analysis plan, identify the relevant CMS research question(s) that will be addressed, cite the location of the detailed analysis plan for those questions in the protocol, provide a statement addressing how the study satisfies each of the standards of scientific integrity (1. through 17. listed above), and the

investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: TAVR CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850
Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov
Email subject line: "CED [NCD topic (i.e. TAVR)] [name of sponsor/primary investigator]"

II.TAVR is covered for uses that are not expressly listed as an FDA-approved indication for AS, including any use for aortic regurgitation, when the conditions in provisions BI2, BI3, and BI4 (CED, § 1862(a)(1)(E) of the Act) above are met as to that particular use.

C. Nationally Non-covered Indications

N/A

D. Other

In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) for any other beneficiary seeking coverage for TAVR. This NCD does not apply to use of TAVR in emergency scenarios.

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Nothing in this NCD precludes coverage of TAVR through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.

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