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Interpreting the New NCD: What It Means for Patients and Programs

Tamara Syrek Jensen

Rubrum Advising · Former Director, Coverage and Analysis Group, CMS

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By the numbers

~30

updates from 2019 to the 2026 final

TAVR is mature. More flexibility, and with it some uncertainty.

~15

revisions from the proposal to the final

CMS listened to public comment.

Source: comparison of CMS decision memos CAG-00430R (2019) and CAG-00430R2 (proposed and final, 2026).

2019 TAVR NCD Coverage Criteria

Coverage with Evidence Development (CED) and a mandatory registry

For every patient, no exceptions

Two face-to-face exams

Surgeon and interventionalist must see the patient

Two operators, every case

Surgeon and interventionalist jointly perform TAVR

Hospital volume minimums

Open-heart, aortic valve, and PCI counts; physician headcount

Source: CMS decision memo CAG-00430R (June 21, 2019).

2026 NCD proposal: less national direction, more local judgment

Team review + one in-person visit

Asynchronous review allowed; one in-person visit mandatory

One operator or two

Heart team decision

Operator volume requirements, no hospital minimums

One volume threshold per operator

Quality improvement process required

Each hospital designs its own process

Source: CMS proposed decision memo CAG-00430R2 (June 15, 2026). Asymptomatic coverage under CED and MAC discretion:

The biggest change: CED

Symptomatic severe Aortic Stenosis (AS): CED ends

CED since 2012, renewed in 2019; now covered nationally without CED. Registry not required.

Asymptomatic severe AS: newly covered

Expands indication but under CED, in a study with an active comparator

Off-label study pathway ends

Moderate AS and AR: MAC discretion or a CMS-approved IDE study

Why

“The CED questions posed in the 2019 TAVR NCD have been sufficiently answered …” — CMS

Source: CMS decision memos CAG-00430R (2019) and CAG-00430R2 (final, Sept 10, 2026). Finalized as proposed.

Heart team strengthened: both specialties, full team

Changed after public comment

PROPOSED

Initial heart team evaluation · one independent in-person operator evaluation · other members “may” be included

WHAT COMMENTERS IDENTIFIED

Commenters said the proposal could be read to allow TAVR without surgical evaluation and to make nurses, advanced practice clinicians, and coordinators optional.

FINAL

- Initial evaluation includes input from both cardiac surgery and interventional cardiology
- Advanced practice clinicians, nurses, and administrators are members; other specialties and research personnel as needed
- Experience in “aortic valve diseases,” not only AS
- One in-person operator evaluation (“independent” dropped); a second is covered

Source: CMS decision memo CAG-00430R2, proposed and final decisions, including Section III, Public Comment

A second TAVR operator is covered, not required

Revised based on public comment

PROPOSED

"... not required but may occur ..."

WHAT COMMENTERS IDENTIFIED

Commenters asked CMS to make clear that both operators are covered, including two from the same specialty.

FINAL

"... not required but is covered ... can be from the same specialty or different specialties"

Source: CMS decision memo CAG-00430R2, proposed and final decisions, including Section III, Public Comment

Other TAVR indications, including AR: MAC discretion made explicit

Clarified after public comment · AR review opened

PROPOSED

"In addition to the national coverage described above, MACs may make reasonable and necessary determinations under section 1862(a)(1)(A) for any other beneficiary seeking coverage for TAVR for AS."

WHAT COMMENTERS IDENTIFIED

Commenters said silence on AR, with the off-label study pathway removed, could be read as noncoverage.

FINAL

"In addition to the national coverage described above, MACs may make reasonable and necessary determinations under section 1862(a)(1)(A) for any other beneficiary seeking coverage for TAVR."

MAC discretion was already the default. The final states it for all TAVR indications, including AR. CMS also opened a separate AR review.

Source: CMS decision memo CAG-00430R2, proposed and final decisions, including Section III, Public Comment

What this means for your program

TAVR NCD became Medicare coverage policy on September 10, 2026. More flexibility means more decisions for your program.

IMPLEMENTATION: Usually months later: 8.6 months on average across recent NCDs; 190 days after the 2019 TAVR NCD

REQUIREMENTS IN THE FINAL NCD

Quality	Continuous quality improvement process required; registry participation not required, and alone does not satisfy it
Evaluation	Input from both specialties and one in-person operator visit, documented before procedure day
Operators	One or two, as the heart team decides
Volume	Each operator: 20 transcatheter valves a year, including 15 TAVR (or 40 and 30 over two years)
Asymptomatic	Only in a CMS-approved CED study
AR and moderate AS	MAC discretion or a CMS-approved IDE study

Source: CMS final decision memorandum, TAVR (CAG-00430R2), Appendix A; implementation timing: CMS Reports to Congress on National Coverage Determinations, FY 2020–2025



REFERENCE

TAVR NCD 20.32 across three versions

2019 final decision · 2026 proposed decision · 2026 final decision

● marks a provision that changed between the 2026 proposed and final decisions

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)

Coverage and CED

Provision	2019 final	2026 proposed	2026 final
Indication	Symptomatic aortic stenosis, per FDA-approved indication	Symptomatic severe AS	Symptomatic severe AS
CED, symptomatic AS	Required	Removed; coverage (no CED)	Same
Registry	Mandatory prospective, national, audited registry	Not required	Not required; voluntary participation encouraged
Asymptomatic severe AS	No specific indication; only through the off-label clinical study pathway	Covered under CED	Covered under CED
CED comparator	None required	Active, contemporaneous comparator	Same; details set with each study sponsor

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)

CED questions and study requirements

Provision	2019 final	2026 proposed	2026 final
● **CED questions**	Four registry questions: real-world outcomes, durability, long-term outcomes, contributing factors	TAVR vs SAVR vs surveillance; reintervention, TAVR vs SAVR; can outcomes replace operator volume	“vs SAVR” removed from reintervention question; asks whether “other measures” could replace volume
Study standards	2019 CED criteria	17 AHRQ standards, CMS 2024 CED guidance	Same
● **Future reconsideration**	Not addressed	Would weigh answers to all CED questions and published evidence	Sentence removed
Ongoing CED studies	Not applicable	Approved under the new CED section or IDE	Same

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)

Heart team and patient evaluation

Provision	2019 final	2026 proposed	2026 final
• **Core members**	Cardiac surgeon and interventional cardiologist experienced in AS	At least one of each, experienced in AS, privileged at the performing hospital	At least one of each, experienced in aortic valve diseases, privileged at the performing hospital
• **Other members**	Other physicians, advanced practitioners, nurses, research personnel, administrators	“May include” other physicians, advanced practice clinicians, nurses, research personnel, administrators	Includes advanced practice clinicians, nurses, administrators; other specialties and research as needed
• **Patient evaluation**	Surgeon and interventional cardiologist each examine the patient face-to-face	Asynchronous team evaluation plus an independent in-person evaluation by a TAVR operator; not virtual	Initial evaluation includes surgery and interventional input; in-person by a TAVR operator, not virtual; second evaluation covered

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)

Evaluation content and the procedure

Provision	2019 final	2026 proposed	2026 final
• **What the evaluation weighs**	SAVR, TAVR, medical or palliative therapy	SAVR, TAVR, close surveillance, palliative care; lifetime management; estimated life expectancy	Same options; life expectancy considered within lifetime management
Documentation	Rationale shared with heart team members	Shared with heart team, patient, and clinicians before procedure day	Same
• **Procedure**	Surgeon and interventional cardiologist jointly participate	Joint participation not required; if joint, both must be TAVR operators	Joint participation covered when the heart team decides; same or different specialties

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)

Volume and hospital requirements

Provision	2019 final	2026 proposed	2026 final
Operator volume	Only for teams without TAVR experience: career procedure counts, device training	≥20 transcatheter valve procedures a year incl. ≥15 TAVR, or ≥40 incl. ≥30 TAVR over two years	Same
Hospital volume	Start-up and ongoing thresholds: AVR, TAVR, open-heart, PCI counts; physician headcount	None	None
Hospital infrastructure	On-site valve surgery and interventional cardiology; post-procedure ICU	On-site structural heart interventional and cardiac surgery programs; ICU; continuous quality improvement	Same

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)

Scope: uses outside the national criteria

Provision	2019 final	2026 proposed	2026 final
• **Other uses**	Uses outside FDA indication covered in clinical studies	MAC discretion for other TAVR for AS; NCD does not apply to emergencies	MAC discretion for any other TAVR; emergency use at MAC discretion
• **Aortic regurgitation**	Only through the off-label clinical study pathway	Not addressed	MAC discretion, Clinical Trial Policy, or IDE; separate reconsideration opened
Moderate AS	Covered in CMS-approved CED studies	No national coverage	No national coverage; Clinical Trial Policy, IDE, or MAC discretion

Source: CMS decision memos CAG-00430R (June 21, 2019) and CAG-00430R2 (proposed June 15, 2026; final Sept 10, 2026)