



NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)

MLN Matters Number: MM11660 **Revised**

Related Change Request (CR) Number: 11660

Related CR Release Date: **June 10, 2020**

Effective Date: June 21, 2019

Related CR Transmittal Number:
R10179CP and R10179NCD

Implementation Date: June 12, 2020

Note: We revised this article to reflect a revised CR 11660 issued on June 10, 2020. The CR revisions were for formatting purposes only and did not alter the substance of the article. In the article, we revised the CR release date, the CR transmittal numbers, and the web addresses of the transmittals. All other information remains the same.

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11660 informs MACs that effective June 21, 2019, the Centers for Medicare & Medicaid Services (CMS) will continue coverage of Transcatheter Aortic Valve Replacement (TAVR) under Coverage with Evidence Development (CED) when the procedure is provided for the treatment of symptomatic aortic valve stenosis and according to a Food & Drug Administration (FDA)-approved indication for use with an approved device, in addition to the coverage criteria outlined in the Medicare National Coverage Determinations (NCD) Manual (Pub. 100-03). CMS will also continue coverage of TAVR for uses that are not expressly listed as an FDA-approved indication in clinical studies that meet specific requirements and are approved by CMS.

These changes relate to Chapter 1, Part 1, Section 20.32 of the NCD Manual and Chapter 32, Section 290 of the Medicare Claims Processing Manual (Pub. 100-04). Both relevant sections are attached to CR 11660.

BACKGROUND

TAVR, also known as Transcatheter Aortic Valve Implantation (TAVI), is used to treat aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

On June 21, 2019, CMS issued an NCD to continue covering TAVR under CED. When the procedure is provided for the treatment of symptomatic aortic stenosis and according to an FDA-approved indication for use with an approved device, CED requires that each beneficiary be entered into a qualified national registry. The NCD lists criteria for the physician operators and hospitals that must be met prior to beginning a TAVR program and after a TAVR program is established.

For uses that are not expressly listed as an FDA-approved indication, beneficiaries must be enrolled in qualifying clinical studies. All clinical research study protocols must:

- Address pre-specified research questions
- Adhere to standards of scientific integrity
- Be reviewed and approved by CMS

Approved studies will be posted at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. The submission process for a clinical research study to Medicare is outlined in the NCD.

TAVR is not covered for beneficiaries in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

This reconsideration of TAVR makes changes to criteria for the heart team and the hospital, and to the trial outcomes and the registry questions/criteria. Other than messaging all current claims processing instructions remain.

The key messaging changes are as follows:

- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer report Remittance Advice Remark Code (RARC) N428 on remittances for claims denied for invalid place of service (POS).
- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer accept RARC N29 on remittances for claims billed without modifier -62 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will report Group Code – Contractual Obligation (CO) on remittances for claims billed without modifier -62 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer accept RARC N29 on remittances for claims billed without modifier –Q0 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will report Group Code – CO on remittances for claims billed without modifier –Q0 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer report Medicare Summary Notice (MSN) 16.77 on remittances for claims billed without ICD-10 diagnosis code Z00.6 and returned as unprocessable.

ADDITIONAL INFORMATION

The official instruction, CR 11660, was issued to your MAC regarding this change via two transmittals. The first updates the Medicare Claims Processing Manual at <https://www.cms.gov/files/document/r10179cp.pdf>. The second updates the NCD Manual and it is at <https://www.cms.gov/files/document/r10179ncd.pdf>.

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
June 12, 2020	We revised this article to reflect a revised CR 11660 issued on June 10, 2020. The CR revisions were for formatting purposes only and did not alter the substance of the article. In the article, we revised the CR release date, the CR transmittal numbers, and the web addresses of the transmittals. All other information remains the same.
March 24, 2020	Initial article released.

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