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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 10179 | Date: June 10, 2020 |
| | Change Request 11660 |

Transmittals 4546 dated March 13, 2020, are being rescinded and replaced by Transmittals 10179, dated, June 10, 2020 to update numbering in the NCD manual to align with the final decision memorandum. All other information remains the same.

SUBJECT: NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to inform MACs that effective June 21, 2019, CMS will continue to cover TAVR under Coverage with Evidence Development (CED) when the procedure is furnished for the treatment of symptomatic aortic stenosis and according to an FDA approved indication for use with an approved device, in addition to the coverage criteria outlined in the NCD Manual.

EFFECTIVE DATE: June 21, 2019

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: June 12, 2020

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|--|
| R | 32/290/Transcatheter Aortic Valve Replacement (TAVR) |
| R | 32/290.1/Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012 |
| R | 32/290.1.1/Coding Requirements for TAVR Services Furnished on or After January 1, 2013 |
| R | 32/290.2/Claims Processing Requirements for TAVR Services on Professional Claims |

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions

regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

| | | | |
|-------------|--------------------|---------------------|-----------------------|
| Pub. 100-04 | Transmittal: 10179 | Date: June 10, 2020 | Change Request: 11660 |
|-------------|--------------------|---------------------|-----------------------|

Transmittals 4546 dated March 13, 2020, are being rescinded and replaced by Transmittals 10179, dated, June 10, 2020 to update numbering in the NCD manual to align with the final decision memorandum. All other information remains the same.

SUBJECT: NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)

EFFECTIVE DATE: June 21, 2019

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: June 12, 2020

I. GENERAL INFORMATION

A. Background: 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.

NOTE: CR 7897, Transmittal (TR) 2552, issued September 24, 2012, implemented the initial NCD for TAVR, effective May 1, 2012. CR 8168, TR 2628, issued January 7, 2013, implemented replacement coding to TAVR effective January 1, 2013. CR 8255, TR 2737, issued July 11, 2013, implemented clinical trial number reporting effective July 1, 2013. CR 8537, TR 2827, issued November 29, 2013, implemented replacement CPT coding effective January 1, 2013.

NOTE: TAVR processing instructions for inpatient hospitals, provided in previous Change Request (CR) 7897, have not changed.

B. Policy: On June 21, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) to continue covering TAVR under Coverage with Evidence Development (CED). When the procedure is furnished for the treatment of symptomatic aortic stenosis and according to a Food and Drug Administration (FDA)-approved indication for use with an approved device, CED requires that each patient 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, patients must be enrolled in qualifying clinical studies. All clinical research study protocols must address pre-specified research questions, adhere to standards of scientific integrity and be reviewed and approved by CMS. Approved studies will be posted to the CMS website at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. The process for submitting a clinical research study to Medicare is outlined in the NCD.

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

NOTE: 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 (see below) all current claims processing instructions remain.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

| Number | Requirement | Responsibility | | | | | | | | | |
|--------------|---|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|--|
| | | A/B MAC | | H H H | D M E M A C | Shared- System Maintainers | | | | Other | |
| | | A | B | | | F I S S | M C S | V M S | C W F | | |
| 11660 - 04.1 | <p>Effective for claims with dates of service on and after June 21, 2019, contractors shall continue to cover TAVR through CED when the procedure is furnished for the treatment of symptomatic aortic stenosis and according to an FDA-approved indication for use with an approved device, in addition to the coverage criteria outlined in Pub 100-03, chapter 1, section 20.32 of the NCD Manual and Pub. 100-04, chapter 32, section 290, Medicare Claims Processing Manual.</p> <p>NOTE: Other than the below messaging changes in requirements 2-7, all TAVR claims processing instructions remain the same.</p> | X | X | | | | | | | | |
| 11660 - 04.2 | <p>Business Requirements 2-7 are specific to the various messaging changes necessary for TAVR claims processing because they do not meet the current CAQH/CORE standards as of January 2, 2020 (Committee on Operating Rules for Information Exchange).</p> <p>Effective for TAVR claims processed on and after January 2, 2020, contractors shall no longer report Remittance Advice Remark Code (RARC) N428 on remittances for claims denied for invalid place of service (POS).</p> | X | X | | | | | | | | |
| 11660 - 04.3 | Effective for TAVR claims processed on and after January 2, 2020, contractors shall no longer accept RARC N29 on remittances for claims billed without modifier -62 and returned as unprocessable. | X | X | | | | | | | | |
| 11660 - 04.4 | Effective for TAVR claims processed on and after January 2, 2020, contractors shall report Group Code – Contractual Obligation (CO) on remittances for claims billed without modifier -62 and returned as unprocessable. | X | X | | | | | | | | |
| 11660 - 04.5 | Effective for TAVR claims processed on and after January 2, 2020, contractors shall no longer accept RARC N29 on remittances for claims billed without modifier –Q0 and returned as unprocessable. | X | X | | | | | | | | |
| 11660 - 04.6 | Effective for TAVR claims processed on and after January 2, 2020, contractors shall report Group Code – CO on remittances for claims billed without modifier | X | X | | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | | |
|--------------|--|----------------|---|-------|-------------|---------------------------|-------|-------|-------|-------|--|
| | | A/B MAC | | H H H | D M E M A C | Shared-System Maintainers | | | | Other | |
| | | A | B | | | F I S S | M C S | V M S | C W F | | |
| | -Q0 and returned as unprocessable. | | | | | | | | | | |
| 11660 - 04.7 | Effective for TAVR claims processed on and after January 2, 2020, contractors shall 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. | X | X | | | | | | | | |
| 11660 - 04.8 | Contractors shall not search for claims processed on or after June 21, 2019, but shall adjust any claims brought to their attention as needed. | X | X | | | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | | | |
|--------------|---|----------------|---|--|-------|-------------|---------|--|
| | | A/B MAC | | | H H H | D M E M A C | C E D I | |
| | | A | B | | | | | |
| 11660 - 04.9 | MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter. | X | X | | | | | |

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

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|---------------------------------|---|
| X-Ref Requirement Number | Recommendations or other supporting information: |
|---------------------------------|---|

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Long, 410-786-5702 or Kimberly.Long@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis) , Sarah Fulton, 410-786-2749 or Sarah.Fulton@cms.hhs.gov (Coverage and Analysis) , Cami DiGiacoma, 410-786-5888 or Cami.DiGiacoma@cms.hhs.gov (Institutional Claims)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

290 – Transcatheter Aortic Valve Replacement (TAVR)

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

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.

The most recent reconsideration of the TAVR policy is effective for claims with dates of service on and after June 21, 2019. It makes changes to the criteria for the heart team and the hospital, and to the trial outcomes and the registry questions/criteria. Please see Publication 100-03, National Coverage Determination Manual Part 1, section 20.32, for complete national policy criteria.

HISTORICAL NOTE: CR 7897, Transmittal (TR) 2552, issued September 24, 2012, implemented the initial NCD for TAVR, effective May 1, 2012. CR 8168, TR 2628, issued January 7, 2013, implemented replacement coding to TAVR effective January 1, 2013. CR 8255, TR 2737, issued July 11, 2013, implemented clinical trial number reporting effective July 1, 2013. CR 8537, TR 2827, issued November 29, 2013, implemented replacement CPT coding effective January 1, 2013.

290.1 – Coding Requirements for TAVR Furnished on or After May 1, 2012, through December 31, 2012

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

The following are the applicable Current Procedural Terminology (CPT) codes for TAVR:

0256T: Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach

0257T: Implantation of catheter-delivered prosthetic aortic heart valve; open thoracic approach (eg, transapical, transventricular)

0258T: Transthoracic cardiac exposure (i.e. sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; without cardiopulmonary bypass

0259T: Transthoracic cardiac exposure (i.e. sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; with cardiopulmonary bypass

The following are the *International Classification of Diseases (ICD)-9* procedure codes applicable for TAVR:

35.05: Endovascular replacement of aortic valve

35.06: Transapical replacement of aortic valve

The following are the ICD-10 procedure codes applicable for TAVR:

35.05: 02RF37Z, 02RF38Z, 02RF3JZ, 02RF3KZ

35.06: 02RF37H, 02RF38H, 02RF3JH, 02RF3KH

290.1.1 - Coding Requirements for TAVR Services Furnished on or After January 1, 2013

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

Beginning January 1, 2013, the following are the applicable CPT codes for TAVR:

33361 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach

33362 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral approach

33363 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach

33364 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach

33365 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)

0381T Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical approach (e.g., left thoracotomy)

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014, shall instead use permanent CPT code 33366.

290.2 - Claims Processing Requirements for TAVR Services on Professional Claims *(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)*

Place of Service (POS) Professional Claims

Effective for claims with dates of service on and after May 1, 2012, place of service (POS) code 21 shall be used for TAVR services. All other POS codes shall be denied.

The following messages shall be used when Medicare contractors deny TAVR claims for POS:

Claim Adjustment Reason Code (CARC) 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

Remittance advice remark code (RARC) N428: "Not covered when performed in this place of service."
Beginning January 2, 2020, contractors shall no longer report RARC N428 for claims denied for invalid POS.

Medicare Summary Notice (MSN) 21.25: "This service was denied because Medicare only covers this service in certain settings."

Spanish Version: "El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."

Professional Claims Modifier -62

For TAVR claims *with dates of service* on or after July 1, 2013, contractors shall pay claim lines with 33361, 33362, 33363, 33364, 33365 & 0318T only when billed with modifier -62. Claim lines billed without modifier -62 shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014 shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without modifier -62 as unprocessable:

CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N29: “Missing documentation/orders/notes/summary/report/chart.” *Beginning January 2, 2020, contractors shall no longer report RARC N29 on remittance for claims billed without modifier -62 and returned as unprocessable.*

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

Professional Claims Modifier -Q0

For claims *with dates of service* on or after *January 1*, 2013, contractors shall pay TAVR claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T when billed with modifier-Q0. Claim lines billed without modifier -Q0 shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014, shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without modifier -Q0 as unprocessable:

CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N29: “Missing documentation/orders/notes/summary/report/chart.” *Beginning January 2, 2020, contractors shall no longer report RARC N29 on remittance for claims billed without modifier -Q0 and returned as unprocessable.*

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

Diagnosis Coding

For claims *with dates of service* on or after July 1, 2013, contractors shall pay TAVR claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T when billed with diagnosis code V70.7 (ICD-10 Z00.6). Claim lines billed without diagnosis code V70.7 (ICD-10 Z00.6) shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014 shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without diagnosis code V70.7 (ICD-10 Z00.6) as unprocessable:

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

RARC M76: “Missing/incomplete/invalid diagnosis or condition”

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

Group Code – Contractual Obligation (CO): *Beginning January 2, 2020, contractors shall no longer report Group Code CO on remittances for claims billed without ICD-10 dx Z00.6 and returned as unprocessable.*

MSN 16.77: This service/item was not covered because it was not provided as part of a qualifying trial/study. Spanish version: Este servicio/articulo no fue cubierto porque no estaba incluido como parte de un ensayo clinic/studio calificado. *Beginning January 2, 2020, contractors shall no longer report MSN 16.77 on remittances for claims billed without ICD-10 diagnosis Z00.6 and returned as unprocessable.*

Professional Claims 8-digit ClinicalTrials.gov Identifier Number

For claims *with dates of service* on or after July 1, 2013, contractors shall pay TAVR claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T when billed with the numeric, 8-digit clinicaltrials.gov identifier number preceded by the two alpha characters “CT” when placed in Field 19 of paper Form CMS-1500, or when entered without the “CT” prefix in the electronic 837P in Loop 2300REF02(REF01=P4). Claim lines billed without an 8-digit clinicaltrials.gov identifier number shall be returned as unprocessable.

Beginning January 1, 2014, temporary CPT code 0318T above is retired. TAVR claims with dates of service on and after January 1, 2014 shall instead use permanent CPT code 33366.

The following messages shall be used when Medicare contractors return TAVR claims billed without an 8-digit clinicaltrials.gov identifier number as unprocessable:

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

NOTE: Clinicaltrials.gov identifier numbers for TAVR are listed on our website:
(<http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html>)

290.3 - Claims Processing Requirements for TAVR Services on Inpatient Hospital Claims

(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20)

Inpatient hospitals shall bill for TAVR on an 11X TOB effective for discharges on or after May 1, 2012. Refer to Section 69 of this chapter for further guidance on billing under CED.

Inpatient hospital discharges for TAVR shall be covered when billed with:

- ICD-9 V70.7 through September 30, 2015, ICD-10 Z00.6 for dates of service on or after October 1, 2015, and Condition Code 30.
- An 8-digit clinicaltrials.gov identifier number listed on the CMS website (effective July 1, 2013)

Inpatient hospital discharges for TAVR shall be rejected when billed without:

- *ICD-9 V70.7 through September 30, 2015, ICD-10 Z00.6 for dates of service on or after October 1, 2015, and Condition Code 30.*
- An 8-digit clinicaltrials.gov identifier number listed on the CMS website (effective July 1, 2013)

Claims billed by hospitals not participating in the trial/registry shall be rejected with the following messages:

CARC 50: These are non-covered services because this is not deemed a “medical necessity” by the payer.

RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code:Contractual Obligation (CO)

MSN 16.77: This service/item was not covered because it was not provided as part of a qualifying trial/study. *Spanish version:* Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.