CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2827	**Date: November 29 2013**
	Change Request 8537

SUBJECT: Transcatheter aortic valve replacement (TAVR) - Implementation of Permanent CPT Code

I. SUMMARY OF CHANGES: This change request (CR) is an update to CR 8168, transmittal 2628 dated January 7, 2013, that implemented replacement codes for TAVR claims with dates of service on and after January 1, 2013. Specifically, we are retiring the remaining temporary CPT code 0318T with permanent CPT code 33366 effective January 1, 2013.

EFFECTIVE DATE: January 1, 2014
IMPLEMENTATION DATE: January 6, 2014

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	32/290.1.1/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
R	32/290.3/Claims Processing Requirements for TAVR Services on Inpatient Hospital Claims

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets.

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 obliged 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

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2827	Date: November 29, 2013	Change Request: 8537

SUBJECT: Transcatheter aortic valve replacement (TAVR) - Implementation of Permanent CPT Code

EFFECTIVE DATE: January 1, 2014
IMPLEMENTATION DATE: January 6, 2014

I. GENERAL INFORMATION

A. Background: Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is a new technology for use in treating aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the native aortic valve. The procedure is performed in a cardiac catheterization lab or a hybrid operating room/cardiac catheterization lab with advanced quality imaging and with the ability to safely accommodate complicated cases that may require conversion to an open surgical procedure. The interventional cardiologist and cardiac surgeon jointly participate in the intra-operative technical aspects of TAVR. On May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering TAVR under Coverage with Evidence Development (CED). The policy is available at http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355.

B. Policy: Prior transmittals have been issued related to claims processing for TAVR. Refer to CR 7897, transmittal 2552, issued September 24, 2012, CR 8168, transmittal 2628, issued January 7, 2013, and CR 8255, transmittal 2737, issued July 11, 2013, for complete, historical information.

This change request (CR) is an update to CR 8168, transmittal dated January 7, 2013, that implemented replacement codes for TAVR claims with dates of service on and after January 1, 2013. Specifically, we are retiring the remaining temporary CPT code 0318T - Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical approach (e.g., left thoracotomy) with permanent CPT code 33366 - Transcathether aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy).

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
8537.1	Effective for TAVR claims with dates of service on and after January 1, 2014, contractors shall recognize permanent CPT code 33366 in place of retired, temporary CPT code 0318T. This coding change appears in the January 2014 Medicare Physician Fee Schedule Database and Integrated Outpatient Code Editor updates.		X							X			

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Other
		A	B	HHH					
8537.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X						

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

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): Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage) , Lori Ashby, 410-786-6322 or lori.ashby@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage).

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets.

Section B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do 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.

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

(Rev.2827. Issued: 11-29-13, Effective: 01-01-14, Implementation: 01-06-14)

Beginning January 1, 2013, the following are the applicable Current Procedural Terminology (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 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)

290.2 - Claims Processing Requirements for TAVR Services on Professional Claims

(Rev.2827. Issued: 11-29-13, Effective: 01-01-14, Implementation: 01-06-14)

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."

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 processed on or after July 1, 2013, contractors shall pay claim lines with 0256T, 0257T, 0258T, 0259T, 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.”

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 processed on or after July 1, 2013, contractors shall pay *TAVR* claim lines for 0256T, 0257T, 0258T, 0259T, 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.”

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.”

For claims processed on or after July 1, 2013, contractors shall pay *TAVR* claim lines for 0256T, 0257T, 0258T, 0259T, 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.”

Professional Claims 8-digit *ClinicalTrials.gov Identifier* Number

For claims processed on or after July 1, 2013, contractors shall pay *TAVR* claim lines for 0256T, 0257T, 0258T, 0259T, 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.2827. Issued: 11-29-13, Effective: 01-01-14, Implementation: 01-06-14)

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:

• V70.7 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:
• V70.7 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. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)