CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2628	**Date: January 7, 2013**
	Change Request 8168

SUBJECT: NCD: Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification

I. SUMMARY OF CHANGES: CR 7897, Transmittal 2552, issued September 24, 2012, implemented a new national coverage determination, transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation), a new technology for use in treating aortic stenosis. CR 7897 provided billing/coding instructions that included codes expiring on December 31, 2012. This CR is an update to CR 7897 that implements replacement codes for TAVR claims with dates of service on and after January 1, 2013. Those codes appear in the final Physician Fee Schedule. This CR also clarifies several policy-related issues regarding use of modifier 62 and the documentation requirements, surgical team criteria, and managed care plan claims processing instructions.

EFFECTIVE DATE: January 1, 2013
IMPLEMENTATION DATE: April 1, 2013 (MCS will implement code early on January 25, 2013.)

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

R/N/D	**CHAPTER / SECTION / SUBSECTION / TITLE**
R	32/Table of Contents
N	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
N	32/290.4/Claims Processing Requirements for TAVR Services for Medicare Advantage (MA) Plan Participants

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: 2628	Date: January 7, 2013	Change Request: 8168

SUBJECT: NCD: Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification

EFFECTIVE DATE: January 1, 2013
IMPLEMENTATION DATE: April 1, 2013 (MCS will implement code early on January 25, 2013.)

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 intravascularly 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 cardiothoracic 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). 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, CED requires that each patient be entered into a qualified national registry. In addition, prior to receiving TAVR, face-to-face examinations of the patient are required by two cardiac surgeons to evaluate the patient's suitability for open aortic valve replacement (AVR). 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.

B. Policy: According to CR 7897, TR 2552, issued September 24, 2012, TAVR claims with dates of service on and after May 1, 2012, through December 31, 2012, will be billed with temporary category III CPT codes 0256T, implantation of catheter-delivered prosthetic aortic heart valve: endovascular approach, 0257T, Implantation of catheter-delivered prosthetic aortic heart valve; open thoracic approach (e.g., 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, and those codes are contractor-priced.

TAVR claims with dates of service on and after January 1, 2013, forward, will be billed with five (5) permanent CPT category 1 codes and one (1) temporary category 3 code (33361, 33362, 33363, 33364, 33365 & 0318T). These six (6) codes will replace the four (4) temporary codes that expire on December 31, 2012, (see section IV Supporting Information below). All other claims processing instructions as they relate to TAVR and these new codes have been updated accordingly.

Clarification: For indications that are not approved by the FDA, patients must be enrolled in qualifying clinical studies. The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. Approved studies will be posted on the CMS Web site at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html. The process for submitting a clinical research study to Medicare is outlined in the NCD.

Clarification: The NCD requires an interventional cardiologist and a cardiothoracic surgeon to jointly participate in the intraoperative technical aspects of TAVR as specified in Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, section 20.32. All TAVR codes must be billed with modifier 62 (two (2) surgeons).

Clarification: When a Medicare Advantage (MA) plan participant receives TAVR services, the MA plans are responsible for payment. Medicare coverage for TAVR is included under section 310.1 of the NCD Manual (Routine Costs in Clinical Trials) and it is in these trials that the fee-for-service (FFS) system is responsible for payment.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				Other
		Part A	Part B					F I S S	M C S	V M S	C W F	
8168.1	Effective for claims with dates of service on and after May 1, 2012, contractors shall allow payment for TAVR as outlined in Pub 100-03, chapter 1, section 20.32, of the NCD Manual and Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 290.	X	X		X	X						
8168.2	Effective for dates of service on and after January 1, 2013, forward, contractors shall recognize codes 33361, 33362, 33363, 33364, 33365 & 0318T when billing for TAVR. **NOTE:** These codes appear in the January 2013 MPFSDB update.	X	X		X	X						
8168.3	Contractors shall pay claims for 33361, 33362, 33363, 33364, 33365 & 0318T only when services are provided for in place of service (POS) 21, Inpatient Hospital.		X			X						
8168.3.1	Contractors shall deny claims lines with 33361, 33362, 33363, 33364, 33365 & 0318T with a POS code other than 21. Claim Adjustment Reason Code (CARC) 58: "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.		X			X						

Number	Requirement	Responsibility										
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		Part A	Part B					FISS	MCS	VMS	CWF	
	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." Group Code –Contractual Obligation (CO).											
8168.4	Contractors shall only pay claim lines with 33361, 33362, 33363, 33364, 33365 & 0318T when billed with modifier 62, Two surgeons/co-surgeons.		X			X			X			
8168.4.1	Contractors shall return claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T as unprocessable when billed without modifier 62. 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.” Group Code – Contractual Obligation (CO).		X			X						
8168.5	Contractors shall pay claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T in a clinical research study when billed with modifier Q0, Investigational clinical service provided in a clinical research study that is in an approved clinical research study.		X			X			X			

Number	Requirement	Responsibility										
		A/B MAC		D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				Other
		Part A	Part B					F I S S	M C S	V M S	C W F	
8168.5.1	Contractors shall return the claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T in a clinical trial as unprocessable when billed without a Q0 modifier. 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." Group Code – Contractual Obligation (CO).		X			X						
8168.6	Contractors shall pay claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T in a clinical trial when billed with secondary diagnosis code V70.7 (ICD-10 = Z00.6).		X			X			X			
8168.6.1	Contractors shall return claim lines for 33361, 33362, 33363, 33364, 33365 & 0318T in a clinical research study as unprocessable when billed without secondary diagnosis code V70.7 (ICD-10=Z00.6). 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." Group Code – Contractual Obligation (CO).		X			X						
8168.7	Effective for claims with dates of service on and after January 1, 2013, through the implementation of this CR, contractors shall not mass-adjust claims but may adjust claims that are brought to their attention.	X	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		DME MAC	FI	CARRIER	RHHI	Other
		Part A	Part B					
8168.8	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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		X	X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
8168.2	See attachment

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

V. CONTACTS

Pre-Implementation Contact(s): JoAnna Baldwin, 410-786-7205 or joanna.baldwin@cms.hhs.gov , Pat Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov , Cynthia Thomas, 410-786-8169 or cynthia.thomas2@cms.hhs.gov , Chanelle Jones, 410-786-9668 or chanelle.jones@cms.hhs.gov , Shauntari Cheely, 410-786-1818 or shauntari.cheely@cms.hhs.gov , Sarah Shirey-Losso, 410-786-0187 or sarah.shirely-losso@cms.hhs.gov

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.

Attachment

Attachment

The TAVR HCPCS Codes have an effective date of January 1, 2013. These are their expected payment indicators. (Their RVU values and indicators will be found in the Medicare Physician Fee Schedule Final Rule 2013.)

HCPCS Code	**33361**	**33362**	**33363**	**33364**	**33365**	**0318T**
Procedure Status	**A**	**A**	**A**	**A**	**A**	**C**
Short Descriptor	REPLACE AORTIC VALVE PERQ	REPLACE AORTIC VALVE OPEN	REPLACE AORTIC VALVE OPEN	REPLACE AORTIC VALVE OPEN	REPLACE AORTIC VALVE OPEN	REPLACE AORTIC VALVE TTHORAC
Effective Date	**01/01/2013**	**01/01/2013**	**01/01/2013**	**01/01/2013**	**01/01/2013**	**01/01/2013**
Multiple Procedure Indicator	2	2	2	2	2	2
Bilateral Surgery Indicator	0	0	0	0	0	0
Assistant Surgery Indicator	0	0	0	0	0	0
Co-Surgery Indicator	2	2	2	2	2	2
Team Surgery Indicator	1	1	1	1	1	1
PC/TC	0	0	0	0	0	0
Site of Service	9	9	9	9	9	9
Global Surgery	000	000	000	000	000	YYY
Pre	0.00	0.00	0.00	0.00	0.00	0.00
Intra	0.00	0.00	0.00	0.00	0.00	0.00
Post	0.00	0.00	0.00	0.00	0.00	0.00
Physician Supervision Diagnostic Indicator	09	09	09	09	09	09
Diagnostic Family Imaging Indicator	99	99	99	99	99	99
Type of Service	2	2	2	2	2	2

Long Descriptor	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical approach (e.g., left thoracotomy)

These are the TAVR HCPCS Add-on codes effective January 1, 2013.

HCPCS Code	**33367**	**33368**	**33369**
Procedure Status	**A**	**A**	**A**
Short Descriptor	REPLACE AORTIC VALVE W/BYP	REPLACE AORTIC VALVE W/BYP	REPLACE AORTIC VALVE W/BYP
Effective Date	**01/01/2013**	**01/01/2013**	**01/01/2013**
Multiple Procedure Indicator	0	0	0
Bilateral Surgery Indicator	0	0	0
Assistant Surgery Indicator	0	0	0
Co-Surgery Indicator	0	0	0
Team Surgery Indicator	1	1	1
PC/TC	0	0	0
Site of Service	9	9	9
Global Surgery	ZZZ	ZZZ	ZZZ
Pre	0.00	0.00	0.00
Intra	0.00	0.00	0.00
Post	0.00	0.00	0.00
Physician Supervision Diagnostic Indicator	09	09	09
Diagnostic Family Imaging Indicator	99	99	99
Type of Service	2	2	2

Long Descriptor	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels)	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels)	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery)

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents

(Rev. 2628, 01/07/13)

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

*290.4 - Claims Processing Requirements for TAVR Services for Medicare Advantage (MA)
Plan Participants*

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

(Rev. 2628, Issued 01-07-13; Effective: 01-01-13, Implementation: 04-01-13)

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)

290.2 - Claims Processing Requirements for TAVR Services on Professional Claims

(Rev. 2628, Issued 01-07-13; Effective: 01-01-13, Implementation: 04-01-13)

<u>Place of Service (POS) Professional Claims</u>

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

Effective on or after May 1, 2012, contractors shall pay claim lines with 0256T, 0257T, 0258T, and 0259T only when billed with modifier 62.

Effective on or after January 1, 2013, contractors shall pay claim lines with 33361, 33362, 33363, 33364, 33365 and 0318T only when billed with modifier 62.

Claim lines billed without modifier 62 shall be returned as unprocessable.

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."

RACR N29: "Missing documentation/orders/notes/summary/report/chart."

Professional Clinical Trial Claims

Effective on or after May 1, 2012, contractors shall pay claim lines with 0256T, 0257T, 0258T, and 0259T in a clinical trial when billed with modifier Q0.

Effective for dates of service on or after January 1, 2013, contractors shall pay claim lines for 33361, 33362, 33363, 33364, 33365 and 0318T in a clinical trial when billed with modifier Q0.

Claim lines in a clinical trial billed without modifier Q0 shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return TAVR claims in a clinical trial 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."

RACR N29: "Missing documentation/orders/notes/summary/report/chart."

Effective for dates of service on or after May 1, 2012, contractors shall pay claim lines for 0256T, 0257T, 0258T and 0259T in a clinical trial when billed with secondary diagnosis code V70.7 (ICD-10=Z00.6).

Effective for dates of service on or after January 1, 2013, contractors shall pay claim lines for 33361, 33362, 33363, 33364, 33365 and 0318T in a clinical trial when billed with secondary diagnosis code V70.7 (ICD-10=Z00.6).

Claim lines in a clinical trial billed without secondary diagnosis code V70.7 (ICD-10=Z00.6) shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return TAVR claims in a clinical trial billed without secondary 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.)"

RACR M76: "Missing/incomplete/invalid diagnosis or condition"

290.4 - Claims Processing Requirements for TAVR Services for Medicare Advantage (MA) Plan Participants

(Rev. 2628, Issued 01-07-13; Effective: 01-01-13, Implementation: 04-01-13)

MA plans are responsible for payment of TAVR services for MA plan participants. Medicare coverage for TAVR is included under section 310.1 of the NCD Manual (Routine Costs in Clinical Trials).