CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2552	Date: September 24, 2012
	Change Request 7897

NOTE: Transmittal 2512, dated August 3, 2012, is being rescinded and replaced by Transmittal 2552, dated September 24, 2012, to include revisions to language in the "Summary of Changes" and clarification to the "Policy Section" of the business requirements for the Pub 100-03 and Pub 100-04 documents. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)

I. SUMMARY OF CHANGES: On May 1, 2012, the Centers for Medicare and 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 or participate in a qualifying clinical study.

EFFECTIVE DATE: May 1, 2012
IMPLEMENTATION DATE: January 7, 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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	32/290/Transcatheter Aortic Valve Replacement (TAVR) Furnished on or After May 1, 2012
N	32/290.1/Coding Requirements for Requirements for Transcatheter Aortic Valve Replacement (TAVR) Services Furnished On or After May 1, 2012
N	32/290.2/Claims Processing Requirements for TAVR Services on Professional Claims
N	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: 2552	Date: September 24, 2012	Change Request: 7897

NOTE: Transmittal 2512, dated August 3, 2012, is being rescinded and replaced by Transmittal 2552, dated September 24, 2012, to include revisions to language in the "Summary of Changes" and clarification to the "Policy Section" of the business requirements for the Pub 100-03 and Pub 100-04 documents. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)

Effective Date: May 1, 2012

Implementation Date: January 7, 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 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.

B.   Policy: 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.

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.

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

TAVR claims with dates of service on and after May 1, 2012, will be billed with temporary level 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 (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, and those codes will be contractor-priced. Beginning January 1, 2013, CMS anticipates permanent CPT level 1 codes will replace the above 4 codes for processing TAVR claims. CMS will issue instructions for the permanent CPT level 1 codes in a future CR.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7897-04.1	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 chapter 32, section 290, Medicare Claims Processing Manual.	X		X	X		X				
7897-04.2	Effective for claims with dates of service on and after May 1, 2012, contractors shall recognize codes 0256T, 0257T, 0258T, and 0259T when billed for TAVR.	X			X						
7897-04.2.1	Effective for dates of service on and after May 1, 2012, contractors shall apply contractor pricing to claims containing 0256T, 0257T, 0258T & 0259T when billing for TAVR	X			X						
7897-04.3	Effective for dates of service on or after May 1, 2012, contractors shall pay claims for 0256T, 0257T, 0258T & 0259T only when services are provided for in place of service (POS) 21, Inpatient Hospital.	X			X						
7897-04.3.1	Effective on or after May 1, 2012, contractors shall deny claims lines with 0256T, 0257T, 0258T& 0259T 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. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	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).										
7897-04.4	Effective on or after May 1, 2012 contractors shall only pay claim lines with 0256T, 0257T, 0258T & 0259T when billed with modifier 62, Two surgeons/co-surgeons.	X			X			X			
7897-04.4.1	Effective on or after May 1, 2012 contractors shall return claim lines for 0256T, 0257T, 0258T, and 0259T 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						
7897-04.5	Effective for dates of service on or after May 1, 2012, contractors shall pay claim lines for 0256T, 0257T, 0258T & 0259T 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 (place an "X" in each applicable column)									
		A / B MAC	D M E MAC	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
7897-04.5.1	Effective for dates of service on or after May 1, 2012, contractors shall return the claim lines for 0256T, 0257T, 0258T & 0259T 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						
7897-04.6	Effective for dates of service on or after May 1, 2012, contractors shall pay claim lines for 0256T, 0257T, 0258T & 0259T in a clinical trial when billed with secondary diagnosis code V70.7 (ICD-10 = Z00.6).	X			X			X			
7897-04.6.1	Effective for dates of service on or after May 1, 2012, contractors shall return claim lines for 0256T, 0257T, 0258T & 0259T 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						
7897-04.6.2	Contractors shall **NOT** return claims billed with	X			X						

Number	Requirement	A / B MAC	D M E MAC	F I	C A R R I E R	R H H I	F I S S	M C S	V M S	C W F	OTHER
	modifier Q0 that do not contain an optional clinical trial number in item 23 of the CMS-1500 form or the electronic equivalent.										
7897-04.7	Effective for inpatient hospital discharges on or after May 1, 2012, contractors shall allow payment for TAVR (ICD-9 procedure codes 35.05, Endovascular replacement of aortic valve, or 35.06, Transapical replacement of aortic valve) only when billed with secondary diagnosis code V70.7 and condition code 30.	X		X			X				
7897-04.7.1	Contractors shall note that the appropriate ICD-10 codes are listed below. Contractors shall track the ICD-10 code/edits (and add the code(s)/edit(s) to their system when applicable) and ensure that the updated edit is functional as part of the ICD-10 implementation. • Procedure Code 35.05: 02RF37Z 02RF38Z 02RF3JZ 02RF3KZ • Procedure Code 35.06: 02RF37H 02RF38H 02RF3JH 02RF3KH • Diagnosis Code V70.7 = Z00.6 **NOTE: You will not receive a separate Change Request instructing you to implement updated edits.**	X		X	X		X	X			
7897-04.7.2	Effective for inpatient hospital discharges on or after May 1, 2012, contractors shall reject claims for TAVR when billed without V70.7 and Condition Code 30. 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	X		X			X				

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	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.)										
7897-04.8	Effective for claims with dates of service on and after May 1, 2012, through January 7, 2013, contractors shall not mass-adjust claims but may adjust claims that are brought to their attention.	X		X	X						

III.   PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7897-04.9	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 site and include information about it in a listserv message within one week of the availability of the provider education article. In	X		X	X						

Number	Requirement	A / B MAC	D M E MAC	F I	C A R R I E R	R H H I	FISS	MCS	VMS	CWF	OTHER
							Shared-System Maintainers				
	addition, the provider education article shall be included in your 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.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s):
Practitioner Claims Processing: Cynthia Thomas, (410) 786-8169, cynthia.thomas2@cms.hhs.gov, Chanelle Jones, (410) 786-9668, chanelle.jones@cms.hhs.gov; Institutional Claims Processing: Sarah-Shirey-Losso, 410-786-0187, sarah.shirey-losso@cms.hhs.gov, Shauntari Cheely, (410) 786-1818, Shauntari.cheely@cms.hhs.gov, coverage: JoAnna Baldwin, 410-786-7205, Joanna.Baldwin@cms.hhs.gov, Wanda Belle, 410-786-7491, wanda.belle@cms.hhs.gov, Patti Brocato-Simons, 410-786-0261, patti.brocatosimons@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; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*, include the following statement:

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.

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Medicare Claims Processing Manual
Chapter 32 – Billing Requirements for Special Services

Table of Contents

(Rev.2552, 09-24-12)

290 – Transcatheter Aortic Valve Replacement (TAVR)
(Rev. 2552, Issued: 09-24-12, Effective: 05-01-12, Implementation: 01-07-13)

For services furnished on or after May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) covers transcatheter Aortic Valve replacement (TAVR). See National Coverage Determinations (NCD) Manual (Pub. 100-03) Chapter 20, Section 32 for complete coverage guidelines.

290.1 – Coding Requirements for TAVR Furnished on or After May 1, 2012
(Rev. 2552, Issued: 09-24-12, Effective: 05-01-12, Implementation: 01-07-13)

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 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. 2 –– Claims Processing Requirements for TAVR Services on Professional Claims
(Rev. 2552, Issued: 09-24-12, Effective: 05-01-12, Implementation: 01-07-13)

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
Effective on or after May 1, 2012 contractors shall pay claim lines with 0256T, 0257T, 0258T and 0259T 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 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 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).

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. 3 –– Claims Processing Requirements for TAVR Services on Inpatient Hospital Claims
(Rev. 2552, Issued: 09-24-12, Effective: 05-01-12, Implementation: 01-07-13)

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.

Claims billed by hospitals not participating in the trial, shall be rejected with the following message:

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.)