

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2737	Date: July 11, 2013
	Change Request 8255

Transmittal 2689, dated May 3, 2013, is being rescinded and replaced by Transmittal 2737, dated July 11, 2013 to correct the verbiage in 8255.2 clarifying use of the “CT” prefix. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) – Implementation of Mandatory Reporting of Clinical Trial Number

I. SUMMARY OF CHANGES: This current CR is being issued to require that claims for TAVR carry an approved clinical trial number.

EFFECTIVE DATE: July 1, 2013 - (For claims processed on or after 7/1/13)

IMPLEMENTATION DATE: October 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/revise 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	32/290.2/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: 2737	Date: July 11, 2013	Change Request: 8255
-------------	-------------------	---------------------	----------------------

Transmittal 2689, dated May 3, 2013, is being rescinded and replaced by Transmittal 2737, dated July 11, 2013 to correct the verbiage in 8255.2 clarifying use of the “CT” prefix. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) – Implementation of Mandatory Reporting of Clinical Trial Number

EFFECTIVE DATE: July 1, 2013 - (For claims processed on or after 7/1/13)

IMPLEMENTATION DATE: October 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). The policy is available at <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355>.

Two prior transmittals have been issued related to claims processing for TAVR. Refer to CR 7897, Transmittal 2552, issued September 24, 2012 and CR 8168, Transmittal 2628, issued January 7, 2013 for complete information.

This current CR is being issued to require that claims for TAVR carry an approved clinical trial number. Given that TAVR is covered only under CED, the agency has ensured that the approved clinical trials and approved registry have obtained valid numbers from www.clinicaltrials.gov and that those numbers are maintained on our website at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html>.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement.

Number	Requirement	Responsibility										
		A/B MAC		D M E	F I	C A R I E R	R H I	Shared- System Maintainers				Other
		P a r t A	P a r t B					F I S S	M C S	V M S	C W F	
8255.1	For claims processed on or after July 1, 2013,		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 I	Shared-System Maintainers				Other
		P a r t A	P a r t B					F I S S	M C S	V M S	C W F	
	<p>contractors shall pay claim lines for, 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T only when billed with an 8-digit clinical trial registry number.</p> <p>NOTE: Clinical trial registry numbers for TAVR are listed on our website: (http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html)</p>											
8255.2	<p>For claims processed on or after July 1, 2013, contractors shall accept the numeric, 8-digit clinical trial registry number preceded by the two alpha characters of “CT” when placed in Field 19 of paper Form CMS-1500, or when entered WITHOUT the “CT” prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4).</p> <p>NOTE: The “CT” prefix is required on a paper claim, but it is not required on an electronic claim.</p>		X			X						
8255.3	<p>For claims processed on or after July 1, 2013, contractors shall return the claim lines for, 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T as unprocessable when billed without an 8-digit clinical trial registry number.</p> <p>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.)”</p> <p>RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”</p> <p>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.”</p> <p>Group Code-Contractual Obligation (CO).</p>		X			X						
8255.4	For claims processed on or after July 1, 2013,		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 I	Shared-System Maintainers				Other
		P a r t A	P a r t B					F I S S	M C S	V M S	C W F	
	contractors shall pay claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T only when billed with modifier Q0.											
8255.5	<p>For claims processed on or after July 1, 2013, contractors shall return claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T as unprocessable when billed without Q0 modifier.</p> <p>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.”</p> <p>RARC N29: “Missing documentation/orders/notes/summary/report/chart.”</p> <p>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.”</p> <p>Group Code-Contractual Obligation (CO).</p>		X			X						
8255.6	For claims processed on or after July 1, 2013, contractors shall pay claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T only when billed with secondary diagnosis code V70.7 (ICD-10=Z00.6).		X			X		X				
8255.7	<p>For claims processed on or after July 1, 2013, contractors shall return the claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T as unprocessable when billed without secondary diagnosis code V70.7 (ICD-10=Z00.6).</p> <p>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.)”</p> <p>RARC M76: “Missing incomplete/invalid diagnosis or condition.”</p>		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 I	Shared-System Maintainers				Other
		P a r t A	P a r t B					F I S S	M C S	V M S	C W F	
	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).											
8255.8	Effective for inpatient hospital discharges on or after July 1, 2013, contractors shall allow payment for TAVR when billed with: 1. an 8-digit clinical trial registry number listed on the CMS Website (NOTE: FISS is ensuring the presence of the procedure codes, and associated diagnosis and condition codes per CR 7897).	X			X							
8255.9	Effective for inpatient hospital discharges on or after July 1, 2013, contractors shall reject claims for TAVR when billed without when billed without: 1. an 8-digit clinical trial registry number listed on the CMS Website (NOTE: FISS is ensuring the presence of the procedure codes, and associated diagnosis and condition codes per CR 7897).	X			X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC		D M E M A C	F I	C A R R I E R	R H I	Other
		P a r t A	P a r t B					
8255.10	MLN Article: A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/	X	X		X	X		

Number	Requirement	Responsibility					
		A/B MAC	D M E	F I	C A R R I E R	R H H I	Other
		P a r t A	P a r t B	M A C			
	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.						

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:
	<p>This CR does not eliminate the previous instructions in CRs 7897 & 8168. Please refer to the prior CRs that include additional billing requirements.</p> <p>CR 7897-National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)</p> <p>CR 8168-NCD: Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification</p>

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

V. CONTACTS

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

290.2 - Claims Processing Requirements for *Transcatheter Aortic Valve Replacement (TAVR)* Services on Professional Claims

(Rev.2737, Issued: 07-11-13, Effective: 07-01-13, Implementation: 10-07-13)

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 *transcatheter aortic valve replacement (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 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.

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 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.

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 claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T when billed with secondary diagnosis code V70.7 (ICD-10=Z00.6).

Claim lines 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 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.)”

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 Clinical Trial Number

For claims processed on or after July 1, 2013, contractors shall pay claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T when billed with the numeric, 8-digit clinical trial registry 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 clinical trial registry number shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return TAVR claims billed without an 8-digit clinical trial registry 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: Clinical trial registry 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.2737, Issued: 07-11-13, Effective: 07-01-13, Implementation: 10-07-13)

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.

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

- *V70.7 and Condition Code 30.*
- *An 8-digit clinical trial registry 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 clinical trial registry 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 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.)