

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 13427	Date: September 22, 2025
	Change Request 14149

Transmittal 13343 issued July 31, 2025, is being rescinded and replaced by Transmittal 13427, dated September 22, 2025, to modify business requirement 14149-04.6 to remove OR and replace with AND after the bullet point for ICD-10 code Q22.8. This correction does not make any revisions to Pub. 100-03. All other information remains the same.

SUBJECT: NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to is to make contractors aware of coverage for Transcatheter Tricuspid Valve Replacement (TTVR) on March 19, 2025.

EFFECTIVE DATE: March 19, 2025

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

IMPLEMENTATION DATE: January 5, 2026

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/Table of Contents /Transcatheter Tricuspid Valve Replacement (TTVR)
N	32/413/1/Coding Requirements for TTVR
N	32/413/2/Claims Processing Instructions for TTVR Professional Claims
N	32/413/3/Claims Processing Instructions for TTVR Institutional Claims Policy
N	32/413/4/Messages

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: 13427	Date: September 22, 2025	Change Request: 14149
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Transmittal 13343 issued July 31, 2025, is being rescinded and replaced by Transmittal 13427, dated September 22, 2025, to modify business requirement 14149-04.6 to remove OR and replace with AND after the bullet point for ICD-10 code Q22.8. This correction does not make any revisions to Pub. 100-03. All other information remains the same.

SUBJECT: NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)

EFFECTIVE DATE: March 19, 2025

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

IMPLEMENTATION DATE: January 5, 2026

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make contractors aware of coverage for Transcatheter Tricuspid Valve Replacement (TTVR) on March 19, 2025.

II. GENERAL INFORMATION

A. Background: TTVR is used in the treatment of Tricuspid Regurgitation (TR).

B. Policy: Effective March 19, 2025, the Centers for Medicare & Medicaid Services (CMS) covers TTVR for the treatment of symptomatic TR under Coverage with Evidence Development (CED) according to the criteria outlined in the NCD manual section 20.37.

III. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
14149 - 04.1	Contractors shall allow claims for TTVR for the treatment of symptomatic TR under CED according to the criteria outlined above. Please refer to the NCD Manual, Publication (Pub.) 100-03, Chapter 1, Section 20.37 and Pub. 100-04 Chapter 32, Section 413 for claims processing instructions.	X	X			X	X			
14149 - 04.2	Contractors shall process TTVR claims submitted with International Classification of Diseases, 10th Revision,	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HH H	MAC	FIS S	MC S	VM S	CW F	
	<p>Procedure Coding System (ICD-10-PCS) X2RJ3RA or 02RJ38Z with the following criteria:</p> <ul style="list-style-type: none">• Type of Bill (TOB) 11X, and• ICD-10-CM diagnosis Z00.6 (reported as other diagnosis), and• Value code D4 with the 8-digit National Clinical Trial (NCT), and• Condition code 30, and• ICD-10-CM principal diagnosis is one of the following:<ul style="list-style-type: none">○ I07.1○ I07.2○ I08.1○ I08.2○ I08.3○ I36.1○ I36.2○ Q22.8 <p>Note: If other procedures are being performed at the same time of the TTVR, the services will be considered as appropriate and current payment guidelines apply.</p>									

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
14149 - 04.3	Contractors shall Return to Provider (RTP) TTVR claims submitted with ICD-10-PCS code X2RJ3RA or 02RJ38Z and the TOB is not equal to 11X.	X				X				
14149 - 04.4	Contractors shall RTP TTVR claims submitted with ICD-10-PCS code X2RJ3RA or 02RJ38Z and condition code 30 is not present.	X				X				
14149 - 04.5	Contractors shall RTP TTVR claims submit with ICD-10-PCS code X2RJ3RA or 02RJ38Z and value code D4 with the 8-digit NCT is not present.	X				X				
14149 - 04.6	Contractors shall deny TTVR claims submitted with ICD-10-PCS code X2RJ3RA or 02RJ38Z and billed without one of the following ICD-10-CM principal diagnosis: <ul style="list-style-type: none"> ○ I07.1 ○ I07.2 ○ I08.1 ○ I08.2 ○ I08.3 ○ I36.1 ○ I36.2 ○ Q22.8, AND ○ ICD-10-CM DX Z00.6 is not present (reported as other diagnosis) 	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
14149 - 04.6.1	<p>Contractors shall use the following messages when denying claims:</p> <p>Claim Adjustment Reason Code (CARC) 167: This (these) diagnosis(es) is (are) not covered.</p> <p>Remittance Advice Remark Code (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 www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code (GC) – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability.</p> <p>Use PR when:</p> <ul style="list-style-type: none"> On institutional claims, Occurrence Code 32 is present, and the GA modifier is not present on any lines on the claim. On institutional claims, Occurrence Code 32 is present, and the GA modifier is appended to 	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	<p>the line item with HCPCS 0646T.</p> <p>Medicare Summary Notice (MSN) 15.20: The following policies were used when we made this decision: NCD 20.37.</p> <p>Spanish Version – Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.37.</p>									
14149 - 04.7	<p>Contractors shall process TTVR line-items on professional claims when submitted with Healthcare Common Procedure Coding System (HCPCS) code 0646T in a clinical research study submitted with the following criteria:</p> <p>ICD-10-CM principal diagnosis is one of the following:</p> <ul style="list-style-type: none"> ○ I07.1 ○ I07.2 ○ I08.1 ○ I08.2 ○ I08.3 ○ I36.1 ○ I36.2 ○ Q22.8, and ○ ICD-10-CM diagnosis Z00.6 is present (reported as other diagnosis), and 		X				X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	<ul style="list-style-type: none"> ○ NCT is present, and ○ Q0 modifier is present. 									
14149 - 04.8	<p>Contractors shall deny TTVR claims submitted with HCPCS code 0646T with the following criteria:</p> <ul style="list-style-type: none"> • ICD-10-CM principal diagnosis is not equal to <ul style="list-style-type: none"> ○ I07.1 ○ I07.2 ○ I08.1 ○ I08.2 ○ I08.3 ○ I36.1 ○ I36.2 ○ Q22.8, ○ Z00.6 (reported as other diagnosis) 		X							
14149 - 04.8.1	<p>Contractors shall deny a line-item on claims with the following messages:</p> <p>CARC 167: This (these) diagnosis(es) is (are) not covered.</p> <p>RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage</p>		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	<p>determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code – CO or PR dependent upon liability.</p> <p>Use PR when:</p> <ul style="list-style-type: none"> On professional claims, the GA modifier is appended to the line item with HCPCS 0646T. <p>MSN 15.20: The following policies were used when we made this decision: NCD 20.37.</p> <p>Spanish Version – Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.37.</p>									
14149 - 04.9	<p>Contractors shall return as unprocessable line-items on claims containing HCPCS code 0646T in a clinical research study when billed without modifier Q0 using the following messages:</p> <p>CARC 4: The procedure code is inconsistent with the modifier used.</p>		X				X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HH H		FIS S	MC S	VM S	CW F	
	<p>RARC N519: Invalid combination of HCPCS modifiers.</p> <p>Group Code: CO</p>									
14149 - 04.10	<p>Contractors shall return as unprocessable line-items on claims containing HCPCS code 0646T in a clinical research study when billed without the clinical trial number using the following messages:</p> <p>CARC 16: Claim/service lacks information or has submission/billing error(s).</p> <p>RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or clinical trial number.</p> <p>Group Code: CO</p>		X							
14149 - 04.11	<p>Contractors shall not search their files for TTVR claims processed with DOS or discharge dates between March 19, 2025, and the implementation date of this change request. However, MACs shall adjust those claims that are brought to their attention.</p>	X	X							

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B

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

VI. CONTACTS

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

VII. 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: 1

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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413 – Transcatheter Tricuspid Valve Replacement (TTVR)

413.1– Coding Requirements for TTVR

413.2– Claims Processing Instructions for TTVR Professional Claims

413.3– Claims Processing Instructions for TTVR Institutional Claims

413.4– Messages

413 – Transcatheter Tricuspid Valve Replacement (TTVR)

(Rev. 13427 Issued: 09-22-25, Effective: 03-19-25, Implementation: 01-05-26)

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter tricuspid valve replacement (TTVR) for the treatment of symptomatic tricuspid regurgitation (TR) under Coverage with Evidence Development (CED) according to the criteria outlined in IOM, Pub. 100-03, National Coverage Determination Manual, Ch 1, section 20.37.

413.1 - Coding Requirements for TTVR

(Rev. 13427 Issued: 09-22-25, Effective: 03-19-25, Implementation: 01-05-26)

The following codes are applicable for TTVR:

ICD-10-PCS codes X2RJ3RA - Replacement of Tricuspid Valve with Multi-plane Flex Technology Bioprosthetic Valve, Percutaneous Approach, New Technology Group 10 and 02RJ38Z – Replace tricuspid valve with zooplastic tissue, percutaneous approach CPT code 0646T - Transcatheter tricuspid valve implantation (TTVI)/replacement with a prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed ICD-10 diagnosis codes:

- I07.1*
- I07.2*
- I08.1*
- I08.2*
- I08.3*
- I36.1*
- I36.2*
- Q22.8*
- Z00.6*

413.2 – Claims Processing Instructions for TTVR Professional Claims

(Rev. 13427 Issued: 09-22-25, Effective: 03-19-25, Implementation: 01-05-26)

Professional claims for TTVR in a clinical research study shall be covered when billed with:

- HCPCS code 0646T,*
- ICD-10 Z00.6 (as other diagnosis code),*
- the 8-digit clinical trial identifier number,*
- One of the ICD-10 diagnosis codes listed in section 413.1 as principal diagnosis code*
- Modifier Q0,*

413.3 – Claims Processing Instructions for TTVR Institutional Claims **(Rev. 13427 Issued: 09-22-25, Effective: 03-19-25, Implementation: 01-05-26)**

*Inpatient hospitals shall bill for TTVR on an IIX Type of Bill (TOB).
Inpatient hospital claims for TTVR shall be covered when billed with:*

- *ICD-10-PCS code X2RJ3RA or 02RJ38Z,*
- *ICD-10 Z00.6 (as other diagnosis code),*
- *Condition Code 30,*
- *Value Code D4 to indicate the 8-digit clinical trial identifier number, and*
- *One of the ICD-10 diagnosis codes listed in section 413.1 as principal diagnosis code*

NOTE: When submitting claims for TTVR provided to Medicare Advantage enrollees, hospitals also report condition code 04. Medicare Advantage Organizations are responsible for payment of the service, consistent with Pub. 100-16, chapter 4, section 10.7.3.

413.4 – Messages

(Rev. 13427 Issued: 09-22-25, Effective: 03-19-25, Implementation: 01-05-26)

- *Contractors shall use the following messages when denying claims for TTVR submitted with missing/incorrect ICD-10 diagnosis code (I07.1, I07.2, I08.1, I08.2, I08.3, I36.1, I36.2, Q22.8 and Z00.6):*

*Claim Adjustment Reason Code (CARC) 167: This (these) diagnosis(es) is (are) not covered.
Remittance Advice Remark Code (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 www.cms.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 (GC) – CO (Contractual Obligation) or PR (Patient Responsibility) dependent upon liability.
Use PR when:*

- *On institutional claims, Occurrence Code 32 is present, and the GA modifier is not present on any lines on the claim.*
- *On institutional claims, Occurrence Code 32 is present, and the GA modifier is appended to the line item with HCPCS 0646T.*
- *On professional claims, the GA modifier is appended to the line item with HCPCS 0646T.*

Medicare Summary Notice (MSN) 15.20: The following policies were used when we made this decision: NCD 20.37.

Spanish Version – Las siguientes políticas fueron utilizadas cuando se tomó esta decisión: NCD 20.37.

Contractors shall Return to Provider (RTP) claims for TTVR submitted on TOB other than IIX, or when submitted without condition code 30, or submitted without value code D4 and the 8-digit National Clinical Trial (NCT).

Contractors shall return as unprocessable line-items on claims containing HCPCS code 0646T in a clinical research study when billed without modifier Q0 using the following messages:

CARC 4: The procedure code is inconsistent with the modifier used.

RARC N519: Invalid combination of HCPCS modifiers.

Group Code: CO

Contractors shall return as unprocessable line-items of claims containing HCPCS code 0646T in a clinical research study when billed without the clinical trial number using the following messages:

CARC 16: Claim/service lacks information or has submission/billing error(s).

RARC MA50: Missing/incomplete Investigational Device Exemption number or clinical trial number.

Group Code: CO

NCD:	20.37									
NCD Title:	Transcatheter Tricuspid Valve Replacement (TTVR)									
IOM:	www.cms.gov/manuals/downloads/ncd103c1_Part1.pdf									
MCD:	https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=314									
CR Numbers:	CR14149									
Part A	Rule Description Part A	Proposed HCPCS/ CPT/ ICD-10-PCS Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifiers Part A	Provider Specialty	Proposed MSN Messages Part A	Proposed CARC Messages Part A	Proposed RARC Messages Part A
Part A	Effective March 19, 2025, the Centers for Medicare & Medicaid Services (CMS) covers TTVR for the treatment of symptomatic TR under Coverage with Evidence Development (CED) according to the criteria outlined in the NCD manual section 20.37. MAC A/FISS shall allow claims for Transcatheter Tricuspid Valve Replacement (TTVR) for the treatment of symptomatic Tricuspid Regurgitation (TR) under Coverage with Evidence Development (CED) according to the criteria outlined in the NCD manual section 20.37. Please refer to the NCD Manual, Pub. 100-03, section 20.37 and Pub. 100-04 Chapter 32, Section 413 for claims processing instructions.	see below	n/a	see below	n/a	n/a	n/a	see below	see below	see below
Part A	MAC A/FISS shall process TTVR claims submitted with ICD-10-PCS X2RJ3RA or 02RJ38Z with the following criteria: •Type of Bill (TOB) 11X, and •ICD-10-CM diagnosis Z00.6 (secondary diagnosis), and •Value code D4 with the 8-digit National Clinical Trial (NCT), and •Condition code 30, and •One of the ICD-10 diagnosis codes listed under primary diagnoses list.	X2RJ3RA or 02RJ38Z	n/a	11X	n/a	n/a	n/a	n/a	n/a	n/a
Part A	MAC A/FISS shall Return to Provider (RTP) TTVR claims submitted with ICD-10-PCS code X2RJ3RA or 02RJ38Z, with the following criteria: •TOB is not equal to 11X, or •Condition code 30 is not present, or •Value code D4 with the 8-digit NCT is not present.	X2RJ3RA or 02RJ38Z	n/a	11X	n/a	n/a	n/a	n/a	n/a	n/a
Part A	MAC A/FISS shall deny TTVR claims billed with ICD-10-PCS code X2RJ3RA or 02RJ38Z, with the following criteria: •ICD-10-CM primary diagnosis is not listed, or •Z00.6 (as a secondary) is not present.	X2RJ3RA or 02RJ38Z	n/a	n/a	n/a	n/a	n/a	15.20	167	N386(CO or PR)
Part B	Rule Description Part B	Proposed HCPCS/ CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifiers Part B	Provider Specialty	Proposed MSN Messages Part B	Proposed CARC Messages Part B	Proposed RARC Messages Part B
Part B	Effective March 19, 2025, the Centers for Medicare & Medicaid Services (CMS) covers TTVR for the treatment of symptomatic TR under Coverage with Evidence Development (CED) according to the criteria outlined in the NCD manual section 20.37. MAC B/MCS shall allow claims for Transcatheter Tricuspid Valve Replacement (TTVR) for the treatment of symptomatic Tricuspid Regurgitation (TR) under Coverage with Evidence Development (CED) according to the criteria outlined in the NCD manual section 20.37. Please refer to the NCD Manual, Pub. 100-03, section 20.37 and Pub. 100-04 Chapter 32, Section 413 for claims processing instructions.	see below	n/a	n/a	n/a	see below	n/a	see below	see below	see below
Part B	MAC B/MCS shall process TTVR line-items on professional claims when submitted with HCPCS code 0646T in a clinical research study submitted with the following criteria: •One of the ICD-10 diagnosis codes listed under primary diagnoses list •ICD-10-CM diagnosis Z00.6 is present (as a secondary), and •the 8-digit National Clinical Trial (NCT) is present, and •Q0 modifier is present.	0646T	n/a	n/a	n/a	Q0	n/a	n/a	n/a	n/a

Part B	MAC B shall deny TTVR claims submitted with HCPCS code 0646T with the following criteria: •One of the primary ICD-10 diagnosis codes is not listed •Z00.6 (as a secondary) is not listed	0646T	n/a	n/a	n/a	n/a	n/a	15.20	167	N386(CO or PR)
Part B	MAC B/MCS shall return as unprocessable line-items on claims containing HCPCS code 0646T in a clinical research study when billed without modifier Q0.	0646T	n/a	n/a	n/a	Q0	n/a	n/a	4	N519(CO)
Part B	MAC B shall return as unprocessable line-items on claims containing HCPCS code 0646T in a clinical research study when billed without the clinical trial number.	0646T	n/a	n/a	n/a	n/a	n/a	n/a	16	MA50(CO)
Revision History										
CR14149: New spreadsheet issued.										