

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10985</b>	<b>Date: September 8, 2021</b>
	<b>Change Request 12361</b>

**SUBJECT: Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform MACs that on January 19, 2021, CMS expanded coverage of mitral valve TEER procedures for the treatment of functional mitral regurgitation (MR), and maintained coverage of TEER for the treatment of degenerative MR through coverage with evidence development (CED) and with mandatory registry participation.

**EFFECTIVE DATE: January 19, 2021**

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

**IMPLEMENTATION DATE: October 8, 2021**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	32/340/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation
R	32/340/1/Coding Requirements for Mitral Valve TEER Claims Furnished on or After August 7, 2014
R	32/340/2/Claims Processing Requirements for Mitral Valve TEER Services on Professional Claims

**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:10985	Date: September 8, 2021	Change Request: 12361
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**SUBJECT: Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation**

**EFFECTIVE DATE: January 19, 2021**

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

**IMPLEMENTATION DATE: October 8, 2021**

## I. GENERAL INFORMATION

**A. Background:** Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve (previously named Transcatheter Mitral Valve Repair (TMVR)) is used in the treatment of mitral regurgitation (MR). TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch.

**B. Policy:** On January 19, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a reconsideration of National Coverage Determination (NCD) 20.33 that expanded coverage of mitral valve TEER procedures for the treatment of functional MR, and maintained coverage of TEER for the treatment of degenerative MR through coverage with evidence development (CED) and with mandatory registry participation. Specifically, CMS covers TEER of the mitral valve under CED for the treatment of symptomatic moderate-to-severe or severe functional MR when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to a Food and Drug Administration (FDA)-approved indication. The NCD also includes hospital infrastructure and procedural volume requirements, as well as operator procedural volume requirements.

For uses that are not expressly listed as an FDA-approved indication, patients must be enrolled in qualifying clinical studies. All clinical research study protocols must address pre-specified research questions, adhere to standards of scientific integrity and be reviewed and approved by CMS. Approved studies will be posted to the CMS website at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. The process for submitting a clinical research study to Medicare is outlined in the NCD.

NOTE: TEER of the mitral valve is NOT covered for patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure and for patients with untreated severe aortic stenosis.

NCD 20.33 will expire on January 19, 2031, 10 years from the NCD effective date, if it is not reconsidered during that time. Upon expiration, coverage will be at the discretion of Medicare Administrative Contractors (MACs).

Note: NCD 20.33 has been restructured and renamed (from TMVR to TEER for mitral valve regurgitation) to more clearly lay out coverage requirements and specify what procedures fall under the NCD.

NOTE: Please refer to the following links for claims processing and NCD instructions prior to January 19, 2021:

Change request (CR) 9002, Transmittal (TN) 178, issued December 5, 2014, informed Medicare Administrative Contractors to pay for TMVR under CED and revised the NCD manual to add NCD 20.33:

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R178NCD.pdf>.

CR 9002, TR 3142, issued December 5, 2014, implemented the initial NCD for TMVR, effective August 7, 2014. TR 3241 rescinded and replaced TN 3142 on April 25, 2014: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf>.

CR 9540, TN 1658, issued April 29, 2016, updated claims processing instructions: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1658OTN.pdf>.

CR 9751, TN 1753, issued November 17, 2016, updated claims processing instructions: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1753OTN.pdf>.

CR 10318, TN 2005, issued January 18, 2018, updated claims processing instructions: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R2005OTN.pdf>.

CR 12027, TN 10566, issued January 14, 2021, updated claims processing instructions: <https://www.cms.gov/files/document/r10566otn.pdf>.

CR 12124, TN 10624, issued March 23, 2021, updated claims processing instructions: <https://www.cms.gov/files/document/r10624otn.pdf>.

## II. 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	HHH		FISS	MCS	VMS	CWF	
12361 - 04.1	Contractors shall be aware that effective January 19, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a reconsideration of National Coverage Determination (NCD) 20.33 that expanded coverage of mitral valve TEER procedures for the treatment of functional MR, and maintained coverage of TEER for the treatment of degenerative MR through coverage with evidence development (CED) and with mandatory registry participation. Specifically, CMS covers TEER of the mitral valve under CED for the treatment of symptomatic moderate-to-severe or severe functional MR when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to a Food and Drug Administration (FDA)-approved indication.</p> <p>Please refer to NCD Manual, chapter 1, Section 20.33, and the Claims Processing Manual at chapter 32, section 340, for further policy and claims processing information.</p>									
12361 - 04.2	<p>Contractors shall accept the following procedure and diagnosis codes on claim lines for TEER services:</p> <p>CPT 33418</p> <p>(List separately in addition to code for primary procedure). CPT 33419</p> <p>CPT 0345T - Transcatheter mitral valve repair percutaneous approach via the coronary sinus</p> <p><b>ICD-10 Procedure Code for Mitral Valve TEER Claims</b></p> <p>02UG3JZ – Supplement mitral valve with synthetic substitute, percutaneous approach</p> <p>02UG3JH - Supplemental mitral valve with synthetic substitute, transapical, percutaneous approach</p> <p><b>ICD-10 Diagnosis Codes for Mitral Valve TEER</b></p> <p>I34.0 – Nonrheumatic mitral (valve) insufficiency, or,</p>	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	<p>I34.1 – Nonrheumatic mitral (valve) prolapse, and,</p> <p>Z00.6 - Encounter for examination for normal comparison and control in clinical research program</p> <p>Modifier -Q0</p> <p>Condition code 30</p>									
12361 - 04.2.1	<p>Contractors shall return as unprocessable/return to provider mitral valve TEER claim lines that do not contain the appropriate coding noted in 12361-04.2 and use the following messages:</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>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 <a href="http://www.cms.gov/mcd/search.asp">www.cms.gov/mcd/search.asp</a>. If you do not have web access, you may contact the contractor to request a copy of the NCD.</p> <p>Group Code: CO “(Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)”</p>	X	X							
12361 - 04.3	Contractors shall not search for TEER claims from January 19,	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	2021, until the implementation of this CR, but shall adjust any claims brought to their attention.									

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12361 - 04.4	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	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):** Wanda Belle, Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis) , Shantari Cheely, 410-786-1818 or Shantari.Cheely@cms.hhs.gov (Institutional Claims Processing) , Yvette

Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims Processing) , Sarah Fulton, 410-786-2749 or Sarah.Fulton@cms.hhs.gov (Coverage and Analysis)

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

## **VI. 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**



## **340 – Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation** *(Rev.10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)*

Transcatheter *Edge-to-Edge Repair (TEER)* of the mitral valve (previously named *Transcatheter Mitral Valve Repair (TMVR)*) is used in the treatment of mitral regurgitation (MR). *TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch.*

*The most recent reconsideration of NCD 20.33 (TEER for Mitral Valve Regurgitation (previously named TMVR)) is effective for claims with dates of service on and after January 19, 2021. It expands coverage of mitral valve TEER procedures for the treatment of functional MR and maintains coverage of TEER for the treatment of degenerative MR, through coverage with evidence development (CED) and with mandatory registry participation. It also makes changes to the criteria for the heart team and hospital, and to the registry questions/criteria and the trial requirements and outcomes. For more detailed information see Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Section 20.33.*

For services furnished *between* August 7, 2014 *and January 19, 2021*, the *CMS covered* TMVR for MR when furnished under CED when the treatment *was* furnished for an FDA-approved indication with an FDA-approved device as follows: (1) Treatment of significant, symptomatic, degenerative MR when furnished according to an FDA-approved indication and all CMS coverage criteria are met, and, (2) TMVR for MR uses not expressly listed as FDA-approved indications but only within the context of an FDA-approved, randomized clinical trial that meets all CMS coverage criteria. TMVR *was* non-covered outside CED or for non-MR indications.

*Historical Note: For claims processing instructions from August 7, 2014, through January 19, 2021, please see the following links:*

*Change request (CR) 9002, Transmittal (TN) 178, issued December 5, 2014, informed Medicare Administrative Contractors to pay for TMVR under CED and revised the NCD manual to add NCD 20.33: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R178NCD.pdf>.*

*CR 9002, TR 3142, issued December 5, 2014, implemented the initial NCD for TMVR, effective August 7, 2014. TR 3241 rescinded and replaced TN 3142 on April 25, 2014: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf>.*

*ICD-10 Coding Updates: <https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10>*

### **340.1 – Coding Requirements for *Mitral Valve TEER* Claims Furnished on or After August 7, 2014**

*(Rev.10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)*

#### **Current Procedural Terminology (CPT) Codes for *Mitral Valve TEER* Claims**

*CPT code 33418, Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis, effective January 1, 2015.*

*CPT code 33419, Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis (es) during same session, effective January 1, 2015. (List separately in addition to code for primary procedure).*

0345T - Transcatheter mitral valve repair percutaneous approach via the coronary sinus

#### **ICD-10 Procedure Code for *Mitral Valve TEER* Claims**

02UG3JZ – Supplement mitral valve with synthetic substitute, percutaneous approach

*02UG3JH – Supplemental mitral valve with synthetic substitute, transapical, percutaneous approach*

### **ICD-10 Diagnosis Codes for *Mitral Valve TEER***

I34.0 – Nonrheumatic mitral (valve) insufficiency, or,

*I34.1 – Nonrheumatic mitral (valve) prolapse, and,*

*Z00.6 – Encounter for examination for normal comparison and control in clinical research program*

### **340.2 – Claims Processing Requirements for *Mitral Valve TEER* Services on Professional Claims**

*(Rev.10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)*

#### **Professional Claims Place of Service (POS) Codes for *Mitral Valve TEER* Claims**

Effective for claims with dates of service on and after August 7, 2014, place of service (POS) code 21 shall be used for *mitral valve TEER* services. All other POS codes shall be denied.

The following messages shall be used when Medicare contractors deny *mitral valve TEER* 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.”

Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)

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 Modifiers for *Mitral Valve TEER* Claims**

Effective for claims with dates of service on or after August 7, 2014, contractors shall pay claim lines for *mitral valve TEERs* billed with *the most recent* CPT codes 33418, 33419, and 0345T in a clinical trial when billed with modifier -Q0. *Mitral valve TEER* 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 *mitral valve TEER* claim lines 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.”

*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](http://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: CO “(Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)”

#### **Professional Clinical Trial Diagnostic Coding for *Mitral Valve TEER* Claims**

Effective for claims with dates of service on or after August 7, 2014 contractors shall pay claim lines for *mitral valve TEERs* billed with *the most recent* CPT codes 33418, 33419 and 0345T in a clinical trial when billed *with the most recent ICD-10 diagnosis codes* ICD-10 I34.0 or *I34.1* and secondary ICD-10 diagnosis code Z00.6. *Mitral valve TEER* claim lines in a clinical trial billed without ICD-10 diagnosis code I34.0 or *I34.1* and secondary ICD-10 diagnosis code Z00.6 shall be denied.

The following messages shall be used when Medicare contractors deny *mitral valve TEER* claim lines in a clinical trial billed without secondary ICD-10 diagnosis code Z00.6:

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: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)

MSN 15.20: The following policies [NCD 20.33] were used when we made this decision

Spanish Version: MSN 15.20: Las siguientes políticas [NCD 20.33] fueron utilizadas cuando se tomó esta decisión.

### **Mandatory National Clinical Trial (NCT) Number for *Mitral Valve TEER* Claims**

Effective for claims with dates of service on or after August 7, 2014, contractors shall pay *mitral valve TEER* claim lines billed with *the most recent* CPT codes *33418, 33419*, and 0345T in a clinical trial only when billed with an 8-digit national clinical trial (NCT) number. Contractors shall accept the numeric, 8-digit NCT 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). **NOTE:** The “CT” prefix is required on a paper claim, but it is not required on an electronic claim. *Mitral valve TEER* claim lines in a clinical trial billed without an 8- digit NCT number shall be returned as unprocessable.

The following messages shall be used when Medicare contractors return *mitral valve TEER* claim lines as unprocessable when billed without an 8-digit NCT number:

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.”

Group Code: CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file.)

### **340.3 - Claims Processing Requirements for *Mitral Valve TEER* Services on Inpatient Hospital Claims**

***(Rev.10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)***

Inpatient hospitals shall bill for *mitral valve TEER* on an 11X type of bill (TOB) effective for discharges on or after August 7, 2014. Refer to Section 69 of this chapter for further guidance on billing under CED.

In addition to the ICD-10 procedure and diagnosis codes mentioned above, inpatient hospital discharges for *mitral valve TEER* shall be covered when billed with the following clinical trial coding:

- Secondary ICD-*10* diagnosis code Z00.6
- Condition Code 30
- Value code D4 - Clinical Trial Number Assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website

Inpatient hospital discharges for *mitral valve TEERs* shall be denied when billed without the ICD-10 diagnosis, procedure codes and clinical trial coding mentioned above. Claims that do not include these required codes 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: CO (Contractual Obligation) assigning financial liability to the provider

MSN 15.20: The following policies [NCD 20.33] were used when we made this decision

Spanish Version: MSN 15.20 - Las siguientes políticas [NCD 20.33] fueron utilizadas cuando se tomó esta decisión.

### **340.4 - Claims Processing Requirements for *Mitral Valve TEER* Services for Medicare Advantage (MA) Plan Participants**

***(Rev.10985; Issued:09-08-21, Effective:01-19-21; Implementation:10-08-21)***

MA plans are responsible for payment of *mitral valve TEER* services for MA plan participants. Medicare coverage for *mitral valve TEERs* is not included under section 310.1 of the NCD Manual (Routine Costs in Clinical Trials).

<b>NCD:</b>	20.33		
<b>NCD Title:</b>	Transcatheter Mitral Valve Repair (TMVR)		
<b>IOM:</b>	<a href="http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAgAAAA%3d%3d&amp;">http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAgAAAA%3d%3d&amp;</a>		
<b>MCD:</b>	<a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf</a>		
		<b>ICD-10 CM</b>	<b>ICD-10 DX Description</b>
			<b>Primary ICD Diagnosis Code</b>
		I34.0	Nonrheumatic mitral (valve) insufficiency
		I34.1	Nonrheumatic mitral (valve) prolapse
			<b>Secondary ICD Diagnosis Code</b>
		Z00.6	Encounter for examination for normal comparison and control in clinical research program

<b>NCD:</b>	20.33		
<b>NCD Title:</b>	Transcatheter Mitral Valve Repair (TMVR)		
<b>IOM:</b>	<a href="http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAqAAAA%3d%3d&amp;">http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAqAAAA%3d%3d&amp;</a>		
<b>MCD:</b>	<a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf</a>		
		<b>ICD-10 PCS</b>	<b>ICD-10 PCS Description</b>
		02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach
		02UG3JH	Supplement mitral valve with synthetic substitute, transapical, percutaneous approach
			<b>CMS reserves the right to add or remove codes associated with its NCDs in order to implement those NCDs in the most efficient manner within the confines of the policy.</b>

<b>NCD:</b> 20.33										
<b>NCD Title:</b> Transcatheter Mitral Valve Repair/Transcatheter Edge-to-Edge Repair (TMVR/TEER) (CR9002, CR9540, CR9751, CR10318, CR12027, CR12124, CR12279, CR12361)										
<b>IOM:</b> <a href="http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAqAAA%3d%3d&amp;">http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAqAAA%3d%3d&amp;</a>										
<b>MCD:</b> <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf">https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf</a>										
Part A	Rule Description Part A	Proposed HCPCS/CPT Part A	Frequency Limitations	TOB (Part A)	Revenue Code Part A	Modifier Part A	Provider Specialty	Proposed MSN Message Part A	Proposed CARC Message Part A	Proposed RARC Message Part A
	<p><b>A/MACs:</b> Effective 1/19/21, CMS reconsideration of NCD 20.33 expanded coverage of mitral valve TEER procedures for the treatment of functional MR, and maintained coverage of TEER for the treatment of degenerative MR through CED and with mandatory registry participation. Specifically, CMS covers TEER of the mitral valve under CED for the treatment of symptomatic moderate-to-severe or severe functional MR when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication. The NCD also includes hospital infrastructure and procedural volume requirements, as well as operator procedural volume requirements.</p> <p>For uses that are not expressly listed as an FDA-approved indication, patients must be enrolled in qualifying clinical studies. All clinical research study protocols must address pre-specified research questions, adhere to standards of scientific integrity and be reviewed and approved by CMS.</p> <p><b>NOTE:</b> TEER of the mitral valve is NOT covered for patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure and for patients with untreated severe aortic stenosis.</p> <p>NCD 20.33 will expire on 1/19/31, 10 years from the NCD effective date, if it is not reconsidered during that time. Upon expiration, coverage will be at the discretion of the MACs.</p>	See ICD Procedure tab		11X						
Part A	<p><b>A/MACs:</b> shall allow payment for TMVR, ICD-10 PCS 02UG3JZ, 02UG3JH, only when billed with secondary dx Z00.6 and condition code 30, Group Code CO.</p>	See ICD Procedure tab		11X				15.20	50	N386

R10985CP1

Rule Description

<b>NCD:</b> 20.33										
<b>NCD Title:</b> Transcatheter Mitral Valve Repair/Transcatheter Edge-to-Edge Repair (TMVR/TEER) (CR9002, CR9540, CR9751, CR10318, CR12027, CR12124, CR12279, CR12361)										
<b>IOM:</b> <a href="http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAqAAA%3d%3d&amp;">http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=273&amp;bc=ACAAAAAAqAAA%3d%3d&amp;</a>										
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<b>Part A</b>	<p><b>A/MACs:</b> shall note appropriate ICD-10 codes 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 ICD-10 implementation.</p> <p>ICD-10 PCS: 02UG3JZ – supplement mitral valve with synthetic substitute, percutaneous approach</p> <p>ICD-10 primary dx: 134.0 – nonrheumatic mitral (valve) insufficiency or <b>134.1 – nonrheumatic mitral valve prolapse</b></p> <p>ICD-10 secondary dx: Z00.6 - Encounter for examination for normal comparison and control in clinical research program</p>	See ICD Procedure tab						15.20	50	N386
<b>Part A</b>	<p>Effective for inpatient hospital discharges on or after 8/7/14, contractors shall allow payment for TMVR for MR under CED only when billed with the following procedure, diagnosis, and clinical trial codes:</p> <p>ICD-10 02UG3JZ, <b>02UG3JH</b></p> <ul style="list-style-type: none"> <li>• ICD-9 primary dx 424.0 – mitral valve disorder (ICD-10 134.0 or 134.1)</li> <li>• ICD-9 secondary dx V70.7 - Exam-clinical trial (Examination of participant in clinical trial) (ICD-10 Z00.6)</li> <li>• Condition code 30 - Qualifying Clinical Trials</li> <li>• 8-digit NCT Number</li> </ul>	See ICD Procedure tab						15.20	50	N386
<b>Part A</b>	<p>Effective for claims with DOS on or after 8/7/14, contractors shall pay TMVR for MR claim lines CPT 0343T(33418), 0344T(33419), and 0345T only when billed with an 8-digit national clinical trial (NCT) number.</p>	See ICD Procedure tab								



# R10985CP1

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<b>Part A</b>	<p><b>A/MACs:</b> for claims with DOS on or after 8/7/14, shall return TMVR for MR claim lines as unprocessable when billed without an 8-digit NCT number using the following messages:            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.            Group Code-CO.</p>					See ICD Procedure tab						16		MA50	

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Part B	Rule Description Part B	Proposed HCPCS/CPT Part B	Frequency Limitations	POS (Part B)	n/a	Modifier Part B	Provider Specialty	Proposed MSN Message Part B	Proposed CARC Message Part B	Proposed RARC Message Part B
	<p><b>B/MACs:</b> Effective 1/19/21, CMS reconsideration of NCD 20.33 expanded coverage of mitral valve TEER procedures for the treatment of functional MR, and maintained coverage of TEER for the treatment of degenerative MR through CED and with mandatory registry participation. Specifically, CMS covers TEER of the mitral valve under CED for the treatment of symptomatic moderate-to-severe or severe functional MR when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication. The NCD also includes hospital infrastructure and procedural volume requirements, as well as operator procedural volume requirements.</p> <p>For uses that are not expressly listed as an FDA-approved indication, patients must be enrolled in qualifying clinical studies. All clinical research study protocols must address pre-specified research questions, adhere to standards of scientific integrity and be reviewed and approved by CMS.</p> <p>NOTE: TEER of the mitral valve is NOT covered for patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure and for patients with untreated severe aortic stenosis.</p> <p>NCD 20.33 will expire on 1/19/31, 10 years from the NCD effective date, if it is not reconsidered during that time. Upon expiration, coverage will be at the discretion of the MACs.</p>	<p>0343T 0344T 0345T 33418 1/1/15 33419 1/1/15</p>		21		Q0				

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<b>Part B</b>	<p><b>B/MACs:</b> shall apply contractor pricing to claims containing CPT 0343T, 0344T &amp; 0345T when billing for TMVR, only when services are provided for in POS 21, Inpatient Hospital. Contractors shall deny claims lines with CPT 0343T, 0344T &amp; 0345T with a POS other than 21. Group Code-CO.</p> <p><b>NOTE:</b> Effective for claims with DOS on or after 1/1/15, CPT 0343T is replaced by CPT 33418 and CPT 0344T is replaced by CPT 33419</p>	0343T 0344T 0345T 33418 1/1/15 33419 1/1/15						21	Q0	21.25	58	
<b>Part B</b>	<p><b>B/MACs:</b> shall only pay claim lines with CPT 0343T, 0344T &amp; 0345T when billed with modifier 62, Two surgeons/co-surgeons from 8/7/14 - 4/6/15. Modifier -62 requirement is removed/implemented 4/6/15.</p> <p>B/MACs shall pay claim lines for CPT 0343T, 0344T &amp; 0345T in a clinical research study when billed with modifier -Q0.</p>	0343T 0344T 0345T 33418 1/1/15 33419 1/1/15					21	62 (8/7/14-4/6/15 only) Q0			4	N386
<b>Part B</b>	<p><b>B/MACs &amp; MCS:</b> shall pay claim lines for CPT 0343T, 0344T &amp; 0345T in a clinical research study when billed with secondary dx Z00.6.</p> <p><b>B/MACs &amp; MCS:</b> shall return same claim lines as unprocessable when billed without the -Q0 modifier. MCS 072L</p> <p><b>B/MACs &amp; MCS:</b> shall deny same claim lines billed without the appropriate primary dx I34.0 or I34.1 and secondary dx Z00.6. MCS 073L Group Code-CO.</p>	0343T 0344T 0345T 33418 1/1/15 33419 1/1/15					21	Q0	15.20	50		N386
	<p><b>B/MACs:</b> effective for claims with DOS on or after 8/7/14, contractors shall pay TMVR for MR claim lines CPT 0343T(33418), 0344T(33419), and 0345T only when billed with an 8-digit national clinical trial (NCT) number.</p>	0343T 0344T 0345T 33418 1/1/15 33419 1/1/15									16	N386

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<b>Part B</b>	<p><b>B/MACs</b> for claims with DOS on or after 8/7/14, shall return TMVR for MR claim lines as unprocessable when billed without an 8-digit NCT number using the following messages:                  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 RARC that is not an ALERT.)                  RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.                  Group Code-CO.</p>	0343T 0344T 0345T 33418 1/1/15 33419 1/1/15							16	MA50
<b>Part B</b>	<p><b>B/MACs:</b> effective for claims with DOS on or after 8/7/14, shall recognize CPT 0343T(<b>33418</b>), 0344T(<b>33419</b>), and 0345T when billed for TMVR for MR.</p>	0343T 0344T <b>0345T</b> 33418 1/1/15 33419 1/1/15		21			Q0			
<b>Revision History</b>	<p><b>CR9540:</b> Add ICD-10 dx code I34.1.                  Remove ICD-10 dx I34.8 because it could include non-covered stenosis.                  Modifier -62 requirement was removed per CR9002, 4/24/15, implemented 4/6/15.  <b>CR9751:</b> 'OR' added to line 8 and 9 to read 134.0 OR 134.1 for clarity. Additional ICD-10 2017                  PCS codes added to procedure tab, effective 10/1/16.                  Update CARC/RARC messages per CORE.  <b>CR10318:</b> Add ICD-10 PCS 02WG37Z, 02WG38Z, 02WG3JZ, 02WG3KZ effective 10/1/17.                  FISS to add ICD-10 02UG3KZ effective 10/1/16 (FISS RC 59266).                  Delete RARC M51, delete CARC 96, add CARC 58 to align with RARC N386 on line 14. Delete RARC N569 replace with RARC N517, delete CARC 16, replace with CARC 50 on line 16. to align with CORE requirements. Clarify messaging verbiage line 16.  <b>CR12027:</b> Add ICD-10 PCS 02UG3JH effective 10/1/20 (FISS RC 59266).  <b>CR12124:</b> Delete ICD-10 procedure codes effective 7/1/2021: 02QG3ZE, 02QG4ZE, 02UG37E, 02UG38E, 02UG3JE, 02UG3KE, 02UG3KZ, 02UG47E, 02UG48E, 02UG4JE, 02UG4KE, 02WG37Z, 02WG38Z, 02WG3JZ, 02WG3KZ. (FISS RC 59266)  <b>CR12279:</b> Added back ICD-10 PCS 02UG3JH inadvertently removed, no action necessary.  <b>CR12361:</b> Update spreadsheet to align with 1/19/21 reconsideration of NCD 20.33 and . No edits necessary.</p>									