| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-03 Medicare National Coverage Determinations | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 10985** | **Date: September 8, 2021** |
| | **Change Request 12361** |

**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.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

**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.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| R | 1/20/33/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation |

**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. 100-03 | Transmittal: 10985 | Date: September 8, 2021 | Change Request: 12361 |
|---|---|---|---|

**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 | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | MAC | FISS | MCS | VMS | CWF | |
| 12361 - 03.1 | 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 cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR | X | X | | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME | Shared-System Maintainers | | | | Other |
| | | A | B | HHH | MAC | FISS | MCS | VMS | CWF | |
| | when furnished according to a Food and Drug Administration (FDA)-approved indication.<br><br>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. | | | | | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| 12361 - 03.2 | 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):** Sarah Fulton, 410-786-2749 or Sarah.Fulton@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Shantari Cheely, 410-786-1818 or Shantar.Cheely@cms.hhs.gov (Institutional Claims Processing) , Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov (Professional Claims Processing) , Patricia Brocato-Simons, 410-786-7491 or Patricia.Brocato-Simons@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: 0**

# NCD 20.33 - *Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation*

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

## A. General

*Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve* is used in the treatment of mitral regurgitation. *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. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers *TEER of the mitral valve* under Coverage with Evidence Development (CED) with the following conditions:

A. *For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (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 and when all of the following conditions are met:

1. The procedure is furnished with a *mitral valve TEER* system that has received FDA premarket approval (PMA).

2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multidisciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. *The heart team must include the following members with experience and training as specified:*

    a. *Cardiac surgeon*
        i. *With ≥ 20 mitral valve surgeries per year or ≥ 40 over two years, 50% of which are mitral valve repairs; and,*
        ii. *Who is board eligible or certified in cardiothoracic surgery or similar foreign equivalent.*
    b. *Interventional cardiologist*
        i. *With professional experience of ≥ 50 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and,*
        ii. *With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and,*
        iii. *Who is board eligible or certified in interventional cardiology or similar foreign equivalent.*
    c. *Interventional echocardiographer (cardiologist or anesthesiologist)*
        i. *With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and,*
        ii. *Who is board eligible or certified in transesophageal echocardiography with advanced training as required for privileging by the hospital where the TEER is performed.*
    d. *Heart failure cardiologist experienced in treating patients with advanced heart failure (only required for functional MR patients); and,*
    e. *Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel, and administrators.*

3. *Each patient's suitability for surgical mitral valve repair, TEER, or palliative therapy must be evaluated, documented, and made available to other heart team members. Additionally, for patients with functional MR, the heart team heart failure cardiologist must document that the patient has persistent symptoms despite maximally tolerated GDMT and cardiac resynchronization therapy, if appropriate, as described below:*

a. *For patients with functional MR: the heart team interventional cardiologist and heart team heart failure cardiologist independently evaluate the patient using information in the medical record and a face-to-face examination. To decrease patient burden, the heart team heart failure cardiologist may meet this requirement through a review of the patient's records and images if the patient has an established relationship with a cardiologist experienced in treating patients with advanced heart failure.*
b. *For patients with degenerative MR: the heart team interventional cardiologist and heart team cardiac surgeon must independently evaluate the patient using information in the medical record and a face-to-face examination.*

4. *An interventional cardiologist or cardiac surgeon from the heart team* must perform the *mitral valve TEER and an interventional echocardiographer from the heart team must perform transesophageal echocardiography during the procedure. The interventional echocardiographer may not also furnish anesthesiology during the same procedure. The interventional cardiologist and cardiac surgeon* may jointly participate in the intra-operative technical aspects of *TEER* as appropriate. *All physicians who participate in the procedure must have device-specific training as required by the manufacturer.*

5. *Mitral valve TEERs* must be furnished in a hospital with appropriate infrastructure and experience that includes, but is not limited to:
   a. On-site *heart valve surgery and interventional cardiology programs;*
   b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart procedures;
   c. *Hospital volume requirements below must be met and maintained:*
      i. ≥ 2*0* mitral valve surgical procedures for severe MR per year *or ≥ 40 over two years*, of which at least 10 *(or 20 over two years)* must be mitral valve repairs; *and,*
      ii. *≥ 2 physicians with cardiac surgery privileges* experienced in valvular surgery; *and,*
      iii. *≥ 1 physician with interventional cardiology privileges; and,*
      iv. *≥ 300* percutaneous coronary interventions (PCIs) per year.

6. The heart team and hospital are participating in a prospective, national, audited registry that: 1) *comprehensively* enrolls *TEER* patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 *Code of Federal Regulations (CFR)* Part 46 and 21 CFR Parts 50 & 56.

   The following outcomes must be tracked by the registry, and the registry must be designed to permit identification and analysis of patient, practitioner, and facility level variables that predict each of these outcomes:

   a. Stroke;
   b. All-cause mortality;
   c. Repeat *TEER* or other mitral procedures;
   d. Transient Ischemic *Attacks* (TIAs);
   e. Major vascular events;
   f. Renal complications;
   g. Functional capacity; *and*
   h. Quality of Life (QoL).

7. The registry *shall* collect all data necessary and have a written executable analysis plan in place to address the following questions. *Specifically, for the CED question d, this must be addressed through a composite metric. For the below CED questions (a-e), the results must be reported publicly as described in CED criterion k.*

   a. When *TEER procedures are* performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?

b. How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
c. What is the long-term (≥ 5 year) durability of the device?
d. What are the long-term (≥ 5 year) outcomes and adverse events?
e. How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

B. *Mitral valve TEERs are covered for* uses that are not expressly listed as an FDA-approved indication when performed within *a clinical study* that fulfills all of the following:

1. *An interventional cardiologist or cardiac surgeon must perform the mitral valve TEER and an interventional echocardiographer must perform transesophageal echocardiography during the procedure. The interventional echocardiographer may not also furnish anesthesiology during the same procedure. The interventional cardiologist and cardiac surgeon* may jointly participate in the intra-operative technical aspects of *TEER* as appropriate. *All physicians who participate in the procedure must have device specific training as required by the manufacturer.*

2. As a fully-described, written part of its protocol, the clinical research trial must critically evaluate the following questions at 12 months or longer follow-up:

   a. What is the rate of all-cause mortality *in the intervention group*?
   b. What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the *intervention group*?
   c. What is the rate of *moderate-to-severe or* severe MR in the *intervention groups*?

3. *As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TEER (minimum 1 year), but must also address at least one of the* following questions:

   a. What is the incidence of stroke?
   b. What is the incidence of TIAs?
   c. What is the incidence of major vascular events?
   d. What is the incidence of renal complications?
   e. What is the incidence of worsening MR?
   f. What is the *change in quality of life after TEER*?
   g. What is the *change in the patient's* functional capacity *after TEER*?

4. The clinical *study* must adhere to the following standards of scientific integrity and relevance to the Medicare population:

   *a.* The principal purpose of the study is to test whether *the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.*
   b. *The rationale for the* study is well supported by available scientific and medical *evidence.*
   c. The study *results are* not *anticipated to* unjustifiably duplicate existing *knowledge.*
   d. The study design is *methodologically* appropriate *and the anticipated number of enrolled subjects is sufficient* to answer the research question*(s)* being asked in the *National Coverage Determination (NCD).*
   e. The study is sponsored by an organization or individual capable of *completing it* successfully.
   f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in *the Code of Federal Regulations (CFR) at* 45 CFR Part 46. If a study is regulated by the *Food and Drug Administration* (FDA*),* it *is* also in

compliance with 21 CFR Parts 50 and 56. *In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and /or services, and the use and eventual disposition of the collected data.*

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity.

h. The study has a written protocol that clearly *demonstrates adherence to* the standards listed *here* as Medicare requirements.

i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. *Such studies may* meet this *requirement* only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the *Agency for Healthcare Quality (*AHRQ*)* Registry of Patient Registries (RoPR).

k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).

l. The study protocol must explicitly discuss *beneficiary* subpopulations affected by *the item or service* under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to *affected beneficiary subpopulations*. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, *the Agency for Healthcare Research and Quality (*AHRQ*)* supports clinical research studies that meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: *TEER* CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

*Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov*
*Email subject line: "CED TEER [name of sponsor/primary investigator]"*

C. Nationally Non-Covered Indications

*TEER of the mitral valve is not covered under the following circumstances:*

1. *For patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure.*
2. *In patients with untreated severe aortic stenosis.*

D. Other

*CMS will consider published, peer-reviewed evidence periodically, following the effective date of this NCD and reconsider the policy when appropriate. The NCD will expire 10 years from the effective date if it is not reconsidered during that time. Upon expiration, coverage will be at the discretion of the Medicare Administrative Contractors.*