

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

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[↪ Terms and Conditions](#)

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<p>Related Medicare Advantage Coverage Summaries</p> <ul style="list-style-type: none"> Experimental Procedures and Items, Investigational Devices and Clinical Trials Transcatheter Heart Valve Procedures

Policy Summary

[↪ See Purpose](#)

Overview

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.

Guidelines

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:

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 an FDA-approved indication and when all of the following conditions are met:

- The procedure is furnished with a mitral valve TEER system that has received FDA premarket approval (PMA).
- The patient (pre-operatively and post-operatively) is under the care of a heart team: a cohesive, multi-disciplinary, 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:
 - Cardiac surgeon
 - With ≥ 20 mitral valve surgeries per year or ≥ 40 over two years, 50% of which are mitral valve repairs; and,
 - Who is board eligible or certified in cardiothoracic surgery or similar foreign equivalent.
 - Interventional cardiologist
 - With professional experience of ≥ 50 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and,
 - With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and,

- Who is board eligible or certified in interventional cardiology or similar foreign equivalent.
 - Interventional echocardiographer (cardiologist or anesthesiologist)
 - With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and,
 - Who is board eligible or certified in transesophageal echocardiography with advanced training as required for privileging by the hospital where the TEER is performed.
 - Heart failure cardiologist experienced in treating patients with advanced heart failure (only required for functional MR patients); and,
 - Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel, and administrators.
- 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:
 - 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.
 - 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.
- 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.
- Mitral valve TEERs must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
 - On-site heart valve surgery and interventional cardiology programs;
 - Hospital volume requirements below must be met and maintained:
 - ≥ 20 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,
 - ≥ 2 physicians with cardiac surgery privileges experienced in valvular surgery; and,
 - ≥ 1 physician with interventional cardiology privileges; and,
 - ≥ 300 percutaneous coronary interventions (PCIs) per year.
- 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:
 - All-cause mortality
 - Stroke
 - Major vascular events
 - Renal complications
 - Functional capacity
 - Repeat TEER or other mitral procedures
 - Transient ischemic attacks (TIAs) and
 - Quality of Life (QoL)
- 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 bullet 5 below, this must be addressed through a composite metric. For the below CED questions, the results must be reported publicly as described in CED criterion k.
 - When TEER procedures are performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
 - How do the demographics of registry patients compare to the pivotal studies?

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

Consistent with section 1142 of the Social Security Act (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.

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:

- 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.
- 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:
 - What is the rate of all-cause mortality in the intervention group?
 - What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the intervention group?
 - What is the rate of moderate-to-severe or severe MR in the intervention groups? 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:
 - What is the incidence of stroke?
 - What is the incidence of renal complications?
 - What is the incidence of worsening MR?
 - What is the incidence of TIAs?
 - What is the incidence of major vascular events?
 - What is the change in quality of life after TEER?
 - What is the change in the patient's functional capacity after TEER?

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

- The item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
- The rationale for the study is well supported by available scientific and medical evidence.
- The study results are not anticipated to unjustifiably duplicate existing knowledge.
- 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).
- The study is sponsored by an organization or individual capable of completing it successfully.
- 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.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity.
- The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare coverage requirements.
- 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 \sim 312.81(a) and the patient has no other viable treatment options.
- 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).
- 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 accessible 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).

- 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 affect 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.
- 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 CMS determines 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 (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]"

Nationally Non-Covered Indications

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

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

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.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: CMS, as part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study. The clinical trial identifier number is required for all items/services provided in relation to

participation in a clinical trial, clinical study, or registry that may result from coverage with evidence development (CED). Specifically, include the clinical trial identifier number if:

- The member is enrolled in an approved clinical trial; and
- The claim is for the investigational item or service, and/or,
- The costs are related to the investigational item or service, and/or
- The costs are related to routine care for the condition in the clinical trial.

See the related MLN Matters.

CPT Code	Description
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

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Condition Code	Description
CED Only	
30	Qualifying clinical trial

Place of Service Code	Description
21	Inpatient hospital

Diagnosis Code	Description
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
CED Only	
Z00.6	Encounter for examination for normal comparison and control in clinical research program

ICD Procedure Code	Description
02QG3ZE	Repair mitral valve created from left atrioventricular valve, percutaneous approach (Deleted 07/01/2021)
02QG4ZE	Repair mitral valve created from left atrioventricular valve, percutaneous endoscopic approach (Deleted 07/01/2021)
02UG37E	Supplement mitral valve created from left atrioventricular valve with autologous tissue substitute, Percutaneous Approach (Deleted 07/01/2021)
02UG38E	Supplement mitral valve created from left atrioventricular valve with zooplastic tissue, percutaneous approach (Deleted 07/01/2021)
02UG3JE	Supplement mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous approach (Deleted 07/01/2021)
02UG3JH	Supplement mitral valve with synthetic substitute, transapical, percutaneous approach
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach
02UG3KZ	Supplement mitral valve with nonautologous tissue substitute, percutaneous approach (Deleted 07/01/2021)
02UG47E	Supplement mitral valve created from left atrioventricular valve with autologous tissue substitute, percutaneous endoscopic approach (Deleted 07/01/2021)

ICD Procedure Code	Description
02UG48E	Supplement mitral valve created from left atrioventricular valve with zooplastic tissue, percutaneous endoscopic approach (Deleted 07/01/2021)
02UG4JE	Supplement mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous endoscopic approach (Deleted 07/01/2021)
02UG4KE	Supplement mitral valve created from left atrioventricular valve with nonautologous tissue substitute, percutaneous endoscopic approach (Deleted 07/01/2021)
02WG37Z	Revision of autologous tissue substitute in mitral valve, percutaneous approach (Deleted 07/01/2021)
02WG38Z	Revision of zooplastic tissue in mitral valve, percutaneous approach (Deleted 07/01/2021)
02WG3JZ	Revision of synthetic substitute in mitral valve, percutaneous approach (Deleted 07/01/2021)
02WG3KZ	Revision of nonautologous tissue substitute in mitral Valve, percutaneous approach (Deleted 07/01/2021)

Questions and Answers

1	Q:	Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development)?
	A:	<ul style="list-style-type: none"> If no, clinical trial number, modifier Q0 diagnosis code Z00.6 should not be submitted. If yes, the three requirements listed above are required. Claims without the required information will be denied.

References

CMS National Coverage Determinations (NCDs)

[NCD 20.33 Transcatheter Mitral Valve Repair \(TMVR\)](#)

CMS Benefit Policy Manual

[Chapter 14; § 20 Food and Drug Administration \(FDA\)-Approved Investigational Device Exemption \(IDE\) Studies](#)

CMS Claims Processing Manual

[Chapter 32; § 340 Transcatheter Mitral Valve Repair \(TMVR\)](#)

CMS Transmittal(s)

[Transmittal 178, Change Request 9002, Dated 12/05/2014 \(Transcatheter Mitral Valve Repair \(TMVR\)-National Coverage Determination \(NCD\)\)](#)

[Transmittal 10515, Change Request 12027, Dated 12/10/2020 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)-April 2021](#)

[Transmittal 10624, Change Request 12124, Dated 03/23/2021 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)-July 2021\)](#)

[Transmittal 10985, Change Request 12361, Dated 09/08/2021 \(Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair \[TEER\] for Mitral Valve Regurgitation\)](#)

MLN Matters

[Article MM9002 Revised, Transcatheter Mitral Valve Repair \(TMVR\)-National Coverage Determination \(NCD\)](#)

[Article MM12027, International Classification of Diseases, 10th Revision \(ICD10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)-April 2021](#)

[Article MM12361, Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair \[TEER\] for Mitral Valve Regurgitation](#)

Other(s)

[CMS Coverage with Evidence Development, CMS Website](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
02/09/2022	<p>Title Change</p> <ul style="list-style-type: none">Previously titled <i>Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33)</i> <p>Supporting Information</p> <ul style="list-style-type: none">Archived previous policy version MPG311.09

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LGAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).