

Transcatheter Mitral Valve Repair (TMVR) (NCD 20.33)

Guideline Number: MPG311.07
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[Terms and Conditions](#)

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Policy Summary

[See Purpose](#)

Overview

Transcatheter mitral valve repair (TMVR) is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation (MR). Abbott Vascular's MitraClipR is the only one with Food and Drug Administration (FDA) approval.

Guidelines

Nationally Covered Indications

TMVR for MR under Coverage with Evidence Development (CED) is covered by the Centers for Medicare & Medicaid Services (CMS) with the following conditions.

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 complete TMVR system that has received FDA premarket approval (PMA) for that system's FDA-approved indication.
- Both a cardiothoracic surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease have independently examined the patient face-to-face and evaluated the patient's suitability for mitral valve surgery and determination of prohibitive risk; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.
- 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.
- TMVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
 - On-site active valvular heart disease surgical program with >2 hospital-based cardiothoracic surgeons experienced in valvular surgery;
 - Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering catheterization laboratory-quality imaging;
 - Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures;

- Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications;
- Non-invasive imaging expertise including transthoracic/transesophageal/3D echocardiography, vascular studies, and cardiac CT studies;
- Adequate outpatient clinical care facilities;
- Appropriate volume requirements per the applicable qualifications below.
- There are institutional and operator requirements for performing TMVR. The hospital must have the following:
 - A surgical program that performs > 25 total mitral valve surgical procedures for severe MR per year of which at least 10 must be mitral valve repairs;
 - An interventional cardiology program that performs > 1000 catheterizations per year, including > 400 percutaneous coronary interventions (PCIs) per year, with acceptable outcomes for conventional procedures compared to National Cardiovascular Data Registry (NCDR) benchmarks;
 - The heart team must include:
 - An interventional cardiologist(s) who:
 - performs > 50 structural procedures per year including atrial septal defects (ASD), patent foramen ovale (PFO) and trans-septal punctures; and;
 - must receive prior suitable training on the devices to be used; and;
 - must be board-certified in interventional cardiology or board-certified/eligible in pediatric cardiology or similar boards from outside the United States;
 - Additional members of the heart team, including: cardiac echocardiographers, other cardiac imaging specialists, heart valve and heart failure specialists, electrophysiologists, cardiac anesthesiologists, intensivists, nurses, nurse practitioners, physician assistants, data/research coordinators, and a dedicated administrator;
 - All cases must be submitted to a single national database;
 - Ongoing continuing medical education (or the nursing/technologist equivalent) of 10 hours per year of relevant material;
 - The cardiothoracic surgeon(s) must be board-certified in thoracic surgery or similar foreign equivalent.
- The heart team fs interventional cardiologist or a cardiothoracic surgeon must perform the TMVR. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.
- The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TMVR 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 mitral valve surgery or other mitral procedures
 - Worsening MR
 - Transient ischemic events (TIAs)
 - Quality of Life (QoL)
- The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):
 - When 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.

TMVR for MR uses that are not expressly listed as an FDA-approved indication when performed within an FDA-approved randomized controlled trial that fulfills all of the following:

- TMVR must be performed by an interventional cardiologist or a cardiac surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.
- 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 group randomized to TMVR compared to the patients randomized to control (surgical repair, optimal medical therapy, or other specified control group)?
 - What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the group randomized to TMVR compared to the patients randomized to control (surgical repair or other specified control group)?
 - What is the rate of severe MR in the group randomized to TMVR compared to the patients randomized to control (surgical repair or other specified control group)?
- The randomized controlled trial must address all of the following questions at one year post- procedure:
 - 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 patient fs post-TMVR QoL?
 - What is the patient fs post-TMVR functional capacity?

The CMS-approved clinical trials and registries must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- The principal purpose of the research study is to test whether a particular intervention potentially improves the participant's health outcomes.
- The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity.
- The research study has a written protocol that clearly addresses, or incorporates by reference; the standards listed as Medicare coverage requirements.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard 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.
- 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 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 research study protocol must explicitly discuss subpopulations affected by the treatment 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 research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. 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, 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 (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: TMVR CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

Nationally Non-Covered Indications

TMVR is non-covered for the treatment of mitral regurgitation when not furnished under CED according to the above-noted criteria. TMVR used for the treatment of any non-mitral regurgitation indications are non-covered.

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
02QG4ZE	Repair Mitral Valve created from Left Atrioventricular Valve, Percutaneous Endoscopic Approach
02UG37E	Supplement Mitral Valve created from Left Atrioventricular Valve with Autologous Tissue Substitute, Percutaneous Approach
02UG38E	Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Percutaneous Approach
02UG3JE	Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Percutaneous Approach
02UG3JH	Supplement Mitral Valve with Synthetic Substitute, Transapical, Percutaneous Approach (Effective 10/01/2020)
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach
02UG3KZ	Supplement Mitral Valve with Nonautologous Tissue Substitute, Percutaneous Approach
02UG47E	Supplement Mitral Valve created from Left Atrioventricular Valve with Autologous Tissue Substitute, Percutaneous Endoscopic Approach
02UG48E	Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach
02UG4JE	Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Percutaneous Endoscopic Approach
02UG4KE	Supplement Mitral Valve created from Left Atrioventricular Valve with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach
02WG37Z	Revision of Autologous Tissue Substitute in Mitral Valve, Percutaneous Approach
02WG38Z	Revision of Zooplastic Tissue in Mitral Valve, Percutaneous Approach
02WG3JZ	Revision of Synthetic Substitute in Mitral Valve, Percutaneous Approach
02WG3KZ	Revision of Nonautologous Tissue Substitute in Mitral Valve, Percutaneous Approach

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](#)

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](#)

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
04/01/2021	Template Update <ul style="list-style-type: none">• Reformatted policy; transferred content to new template
02/10/2021	Supporting Information <ul style="list-style-type: none">• Updated <i>References</i> section to reflect the most current information; no change to guidelines• Archived previous policy version MPG311.06

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, LCAs, 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](#).