



## Medicare Part C Medical Coverage Policy

### Mitral Valve Transcatheter Edge-to-Edge Repair (TEER)

**Origination:** September 17, 2014

**Review Date:** November 14, 2023

**Next Review:** November 2024

**\*\*\* This policy was implemented in the absence of National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) coverage criteria. This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. \*\*\***

#### **DESCRIPTION OF PROCEDURE**

Mitral Valve Transcatheter Edge to Edge Repair (TEER) is used in the treatment of mitral valve regurgitation. The procedure involves clipping together a portion of the mitral valve leaflets as a treatment for reducing mitral regurgitation (MR) with the intended outcomes to improve recovery of the heart from overwork, improve function and potentially halt the progression of heart failure.

#### **DEFINITIONS:**

**Coverage with Evidence Development (CED):** CMS at times, issues a coverage decision with data collection being a part of the condition for coverage. The CED concept considers the item or service to be reasonable and necessary only while evidence is being developed regarding a member's health outcomes in a clinical trial. CMS maintains a registry of facilities that have agreed to the clinical indications specified in the coverage decision. CMS lists clinical trials with CED at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TMVR.html>.

#### **POLICY STATEMENT**

Coverage will be provided for Mitral Valve TEER under CED based on meeting CMS conditions as outlined in the Coverage Decision Advisory, (CAG-00438R).

#### **BENEFIT APPLICATION**

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

### **INDICATIONS FOR COVERAGE**

1. **Preauthorization by the Plan is required; AND**
2. Must be performed in an inpatient facility; **AND**
3. The indication for coverage is symptomatic mitral valve regurgitation; **AND**
4. The device has received FDA premarket approval (PMA); **AND**
5. A cardiac surgeon and a cardiologist experienced in mitral valve surgery and disease have independently examined the member face to face and evaluated the member's suitability for mitral valve surgery with determined risks and have documented their rationale for the TEER; **AND**
6. The participating hospital must be on the TVT (Transcatheter Valve Technology) registry for TEER approved facilities found at <https://www.ncdr.com/TVT/Home/Default.aspx> and request should have a NCT number found at or that is listed on the CMS clinical trial under CED page (link provided in #7).
7. Medicare may cover Mitral Valve TEER for members who have other indications when enrolled in a Medicare qualified clinical trial and registered at <https://clinicaltrials.gov/>. Also, CMS lists the clinical study approvals at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TMVR>.

### **WHEN COVERAGE WILL NOT BE APPROVED**

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

### **BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION**

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 33418, 33419, 0345T

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## **SPECIAL NOTES**

When the above criteria are met, staff will complete an inpatient authorization.

### References:

1. Final Decision Memorandum for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R) Effective on 01/19/2021; viewed online at [NCA - Transcatheter Mitral Valve Repair \(TMVR\) \(CAG-00438R\) - Decision Memo \(cms.gov\)](#) viewed on 2/6/2023.

### Policy Implementation/Update Information:

New Policy: September 17, 2014

Revision Date: March 15, 2017: No updates to coverage criteria. No revisions to policy.

Revision Date: May 17, 2017: Indications for Coverage, #7. Updated hyperlink to <https://www.ncdr.com/TVT/Home/Default.aspx> and removed incorrect link. Removed **AND** from the end of sentence as this is the last criteria on the list.

Revision Date: December 19, 2018; No CMS updates. Removed Indications for Coverage #2. "The Medical Director will review all TMVR requests", Removed Reference #2 as it was no longer valid, and moved "Medicare may cover TMVR for members who have other indications when enrolled in a Medicare qualified clinical trial and registered at <https://clinicaltrials.gov/> . Also, CMS lists the clinical study approvals at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Mitral-Valve-Repair-TMVR.html>" from Special Notes section to Indications for Coverage.

Revision Date: September 18, 2019; Staff Clarification; Reworded Indications for Coverage (6). To say "The participating hospital must be on the TVT (Transcatheter Valve Technology) registry for TMVR approved facilities found at <https://www.ncdr.com/TVT/Home/Default.aspx> and request should have a NCT number found at or that is listed on the CMS clinical trial under CED page (link provided in #7)."

Revision Date: December 16, 2020: Annual Review; No CMS Updates. Minor Revisions Only.

Revision Date: February 17, 2021; CMS Update; Policy Title Changed to Reflect Change in name of Procedure to Mitral Valve Transcatheter Edge-Edge Repair (TEER). Name of procedure updated throughout the policy. Added: When Coverage is not Approved: 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.

Revision Date: February 15, 2023; Annual Review; No CMS updates. Minor Revisions Only

Revision Date: November 15, 2023; Annual Review; No Updates, Minor Revisions Only. Added the following statement to the beginning of policy: "This policy was implemented in the absence of National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) coverage criteria." Statement added to align with the 2024 CMS Final Rule.

## Approval Dates

Medical Coverage Policy Committee: November 15, 2023

Physician Advisory Group/UM Committee: November 14, 2023

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