



Medicare Part C Medical Coverage Policy

Transcatheter Mitral Valve Replacement (TMVR)

Origination: September 17, 2014

Review Date: December 16, 2020

Next Review: December, 2022

******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

Transcatheter Mitral Valve Replacement (TMVR) is a new technology for use in members with 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 TMVR under CED based on meeting CMS conditions as outlined in the Coverage Decision Advisory, (CAG-00438N).

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);

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- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and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. Has to be performed in an inpatient facility; **AND**
3. The indication for coverage is symptomatic mitral valve regurgitation; **AND**
4. The device is FDA approved for symptomatic mitral valve regurgitation; **AND**
5. A cardiac surgeon and a cardiologist experienced in mitral valve surgery and disease have independently examined the patient face to face and evaluated the member's suitability for open mitral valve surgery with determined risks and have documented their rationale for the TMVR; **AND**
6. 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).
7. 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 <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TMVR>.

WHEN COVERAGE WILL NOT BE APPROVED

When the above criteria are not met.

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

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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-00438N) Effective on 08/07/2014; viewed online at www.cms.gov/ viewed on 12/2/20.

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.

Approval Dates:

Medical Coverage Policy Committee: December 16, 2020

Policy Owner: Carolyn Wisecarver, RN, BSN
Title: Medical Policy Coordinator