# Molina Clinical Policy
# Transcatheter Mitral Valve Implantation: Policy No. 437

**Last Approval: 08/14/2024**
**Next Review Due By: August 2025**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

**Mitral valve regurgitation** occurs when blood flows from the left ventricle back into the left atrium of the heart. The mitral valve is the bicuspid valve that connects the left atrium of the heart to the left ventricle. When the valve is functioning properly, it opens allowing the left atrium to pump freshly oxygenated blood into to the left ventricle and closes preventing regurgitation, or backflow, into the left atrium when the left ventricle pumps fresh blood to the rest of the body. Over time, wear or structural changes to the heart can result in the valve not closing properly, resulting in mitral regurgitation (MR). Primary MR results from structural failure of the valve, whereas secondary MR results from left ventricular dysfunction. MR results in the heart having to work harder to oxygenate the body, which leads to an enlarged left ventricle and can ultimately lead to heart failure. The first treatment for MR is guideline directed medical therapy. For patients with severe symptomatic MR after maximally tolerated guideline directed medical therapy, mitral valve repair or replacement may be warranted, with repair being preferable to replacement when feasible (Aldea 2024, Pislaru 2024). Mitral valve repair may be done via the percutaneous or transcatheter method, such as in the transcatheter edge to edge repair that utilizes different technologies (e.g., Mitraclip or Pascal Precision systems) to reduce MR; however, due to variations in anatomy some repair technologies may not be optimal, leading those patients to require a mitral valve implant or replacement.

**Transcatheter mitral valve implantation** (TMVI), also referred to **transcatheter mitral valve replacement** (TMVR), is a minimally invasive intervention aimed to treat MR that would normally require open surgical intervention. During the procedure, a bioprosthetic valve is delivered via a percutaneously inserted catheter and then deployed over the diseased mitral valve, TMVI over a native valve, or over an existing yet dysfunctional bioprosthetic valve, transcatheter valve-in-valve replacement. Less commonly, a transcatheter replacement procedure may be used to treat a calcified mitral valve; however, this procedure involves significantly more risk of complication. At this time, a small low-quality body of evidence suggests TMVI for native mitral valve disease may be effective for elderly patients with severe MR who are high risk candidates for open surgical replacement; however, high quality data validating this is extremely limited to non-existent (Aldea 2024).

**Mitral valve-in-valve replacement** (MViV) uses the minimally invasive transcatheter procedure to place a new valve over an existing prosthetic valve that is no longer functioning properly. Minimally invasive MViV is intended for patients who are at high risk for conventional open mitral valve repair or replacement (Aldea 2024).

### Regulatory Status

There are currently no FDA approved devices for TMVI over a native valve. There are numerous interventional trials currently active or recruiting, including the APOLLO Study (NCT03242642) to evaluate the Medtronic Intrepid™ TMVR System in patients with severe symptomatic MR, and the MISCEND Study (NCT02718001) to evaluate the safety and performance of the Edwards EVOQUE Eos mitral valve replacement system (www.clinicaltrials.gov).

The SAPIEN 3 THV System and SAPIEN 3 Ultra THV System (Edwards Lifesciences) received expanded FDA approval in 2021 for use in individuals with symptomatic heart disease due to failure of a surgical bioprosthetic mitral valve who are at high risk or greater for open surgical treatment.

## RELATED POLICIES

*MCP-184: Experimental and Investigational Services*

*Please refer to MCG S-290 for guidelines on transcatheter mitral valve repair (e.g., Mitraclip) or open surgical intervention for mitral valve repair or replacement.*

## COVERAGE POLICY

Transcatheter mitral valve implantation for native mitral valve disease is considered **experimental, investigational, or unproven** due to insufficient published evidence to assess the safety and/or impact on health outcomes of transcatheter mitral valve implantation in patients with diseased mitral valves.

Transcatheter mitral valve-in-valve implantation using an FDA approved device (e.g., Edwards SAPIEN 3 Transcatheter Heart Valve System or Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System) is **considered medically necessary** when **ALL** the following are met:

1. Symptomatic heart disease due to failing (i.e., stenosed, insufficient, or combined) surgical bioprosthetic mitral valve

2. There is high or greater risk for open surgical therapy (e.g., predicted 30-day risk of surgical mortality ≥8%, based on Society of Thoracic Surgeons [STS] risk score and other clinical co-morbidities unmeasured by the STS risk calculator) as determined by a heart team including a cardiothoracic surgeon

**DOCUMENTATION REQUIREMENTS.** Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

## SUMMARY OF MEDICAL EVIDENCE

### *Transcatheter Mitral Valve Implantation (TMVI)*

There are currently no FDA approved devices for TMVI over a native valve and existing evidence is comprised of observational or retrospective studies of patients who have undergone TMVI for experimental or compassionate use. Further studies with larger numbers of participants are needed to determine safety, appropriate candidate selection, and long-term device durability.

Alperi et al. (2023) conducted a systematic review and included outcomes of 347 patients who underwent TMVR and summarized 30-day outcomes for 12 included studies and mid-term (data after 30 days) outcomes for 8 studies. Of the 8 studies with mid-term outcomes, the mean follow-up time was 17.5 months. Findings noted high technical success rates (95.4%). Thirty-day mortality rate was 8.4% (n = 29). The most common adverse effect in the initial 30 days was life-threatening or major bleeding (15.6%; n = 54). Rate of stroke in the first 30 days was 2.6% (n = 9). Despite a rather high mortality and major bleeding rate, mid-term outcomes showed a statistically significant reduction in both in grade 3+ or greater MR and number of patients with continued New York Heart Association (NYHA) functional class III or greater after intervention.

Ahmed et al. (2023) conducted a systematic review to update the literature on the experience with the Tendyne TMVI system 10 years since its first human implantation. Twenty-six articles were included in the analysis, totaling 319 patients. Patient profiles included mitral annular calcification (MAC) reported in 107 patients (33.5%), preoperative MR grades 1, 2, and 3-4 were reported in 3, 5, and 307 patients, respectively. Technical success was achieved in 309 patients (96.9%) with postoperative MR grades 1, 2, and 4 were reported in 12, 3, and 1 patients respectively. At the

end of follow up, 79 patients died (24.8%) including 52 patients (16.3%) due to cardiovascular causes; however, follow up duration varied greatly among the different studies. The authors concluded that the Tendyne TMVI system appears to be a promising option for minimally invasive MR intervention.

Hungerford et al. (2022) conducted a retrospective observational cohort comparison study to compare patient outcomes between transcatheter edge to edge repair (TEER) and TMVI in treating MR. Fifty patients underwent TEER and 46 underwent TMVI. All patients had comparable MR flow dynamics preoperatively with no significant difference in effective regurgitant orifice area (0.5 ± 0.3 cm2 vs 0.5 ± 0.4 cm2; P = 0.75), proximal isovelocity surface area (P = 0.69), regurgitant fraction (P = 0.55), regurgitant volume (P = 0.24), or vena contracta (P = 0.07). Mitral prostheses were successfully implanted in 96% of TEER and 95.7% of TMVI patients. In the post-surgical TMVI cohort MR was eliminated (grade 0) in 89% of patients prior to discharge, and 100% of TMVI patients had ≤1+ MR at 3 months (P < 0.001); versus 92% of TEER patients had ≤2+ MR prior to discharge, and 70% had ≤1+ MR, but 10% developed ≥ 3+ MR (P < 0.05) at 3 months. Neither group had acute procedural deaths or myocardial infarction, and both groups, had an 86% rate of successful device implantation free of cardiovascular mortality, myocardial infarction, stroke, rehospitalization for heart failure, and device malfunction at 30 days. One-year cardiovascular disease-free survival was 90% in TEER and 81% in TMVI patients (P < 0.0). The authors concluded that while both procedures reduced MR, TMVI achieved a more complete and more durable reduction in MR than TEER; however, more prospective clinical trials are needed to verify this data.

Bapat et al. (2018) reported on an international study investigating the feasibility of the Twelve Intrepid TMVR system (Medtronic, Inc.) in 50 patients with severe MR, NYHA class III or IV, and LVEF of at least 20% at high or extreme surgical risk (NCT02322840). Transapical device implantation was successful in 48 patients. Seven deaths (14%) occurred within the first 30 days; with 3 deaths related to apical access site bleeding, 1 after device malpositioning during the procedure, and 3 due to refractory heart failure. Four additional patients died between 30 days and 4 months post TMVR, with 3 of these deaths due to sudden cardiac arrest and 1 due to non-cardiac causes. At 1 year, survival rate was 76.5%. At the point of last follow up (median 173 days), NYHA was class II or less in 79% of subjects and all subjects MR reduced to mild or trace.

Muller et al. (2017) examined short-term and 30-day outcomes in a prospective cohort early feasibility study comprised of 30 patients who underwent TMVR with the Tendyne Mitral Valve System (Abbott) to for treatment of symptomatic grade 3 (6.9%) or 4 (93.1%) MR (NCT02321514). Device implantation was successful in 28 of the 30 patients and of those, 1 death occurred 13 days following the procedure which was attributable to hospital-acquired pneumonia and 1 incidence of leaflet thrombus requiring increased anticoagulation dosage. During the 30-day follow up period, 4 patients were re-hospitalized requiring treatment for heart failure. Transthoracic echocardiography showed positive results at 30 days with 26 patients showing no MR and the remaining patient showing mild MR, resulting in an overall successful device rate of 83.3%. The primary safety endpoint was freedom from major adverse events which was achieved in 83.3% of participants. Additional participants were enrolled as an expansion of this study, and 1-year outcomes (Sorajja et al. 2019) and 2-year outcomes (Muller et al. 2021) of the first 100 patients were reported. Device implantation was successful in 97 of the 100 patients. At two years, there were 39 deaths among the participants of 34 were cardiovascular in origin, with 17 deaths occurring within the first 90 days post-TMVI. The predominant causes of death were refractory heart failure (n = 14) and fatal arrhythmias (n = 8). At 2 years, 93.2% of the 44 patients available for evaluation had no MR on transthoracic echocardiograph and the remaining 6.8% had mild MR.

***Transcatheter Mitral Valve-In-Valve (MViV)***

Zhou et al. (2023) conducted a systematic review and meta-analysis on transcatheter mitral valve in valve replacement (MViV) versus redo surgical mitral valve replacement (SMVR). Nine retrospective cohort studies were included in the analysis, 1,464 patients underwent MViV and 1,574 patients underwent redo SMVR, totaling 3,038 patients analyzed. The main comparison objectives were comparing in-hospital mortality, stroke, renal dysfunction, vascular complication, pacemaker implantation, exploration for bleeding, paravalvular leak, mean mitral valve gradient, 30-day mortality, and 1-year mortality. MViV outperformed SMVR in the following outcomes: 41 of 1,299 patients (3.2%) in the TMVR group died in hospital compared with 93 of 1,366 patients (6.8%) in the redo SMVR group; MViV was associated with a lower stroke rate compared with redo SMVR (OR: 0.44; 95% CI: 0.29–0.67, P = 0.0001; I2 = 0%, P = 0.73); MViV had a lower rate of renal dysfunction, as SMVR was found to have a statistically significant higher rate of renal issues (OR: 0.52; 95% CI: 0.37–0.75, P = 0.0003; I2 = 0%, P = 0.73); MViV was associated with a lower vascular complication rate than redo SMVR (OR: 0.58; 95% CI: 0.43–0.78, P = 0.004; I2 = 0%, P = 0.94); and two out of 87 patients (2.3%) had an exploration for bleeding in the MViV group compared with 13 of 127 patients (10.2%) in the redo SMVR group.

SMVR outperformed MViV in only one outcome: MViV had a significantly greater rate of paravalvular leak than the redo SMVR group (OR: 22.12; 95% CI: 2.81–174.16, P = 0.003; I2 = 0%, P = 0.55). When analyzed the following outcomes were comparable between the two groups: no significant difference in the mitral valve gradient between the groups (MD: 0.04; 95% CI: −0.47 to 0.55, P = 0.87; I2 = 0%, P = 0.30); no significant difference between the groups in 30-day mortality (OR: 0.65; 95% CI: 0.36–1.17, P = 0.15; I2 = 0%, P = 0.41); and last, no significant difference between the groups in 1-year mortality (OR: 0.96; 95% CI: 0.63–1.45, P = 0.84; I2 = 0%, P = 0.96). The authors concluded that MViV can achieve comparable short-term outcomes while reducing surgical trauma; however, larger randomized prospective studies with longer follow up times are needed to validate these findings.

Zogg et al. (2023) conducted a head-to-head analysis comparing post-discharge outcomes between MViV and redo SMVR. Utilizing the Nationwide Readmissions Database, adult patients aged ≥18 years with failed/degenerated bioprosthetic mitral valves who underwent either isolated MViV or redo SMVR between 2015 to 2019 were analyzed. The risk-adjusted differences in 30-, 90-, and 180-day outcomes were compared using propensity score weighting with overlap weights to mimic the results of a randomized controlled trial. A total of 2,734 patients were analyzed with the groups comprised of 687 MViV patients and 2, 047 redo SMVR patients. After the overlap weighting to attain balance between treatment groups, MViV was associated with significantly lower major morbidity within 30 (odds ratio [95% confidence interval (CI)] 0.0.31 [0.22 to 0.46]), 90 (0.34 [0.23 to 0.50]), and 180 (0.35 [0.24 to 0.51]) days. This difference was driven in lower rates of major bleeding (0.20 [0.14 to 0.30]), new onset complete heart block (0.48 [0.28 to 0.84]) and need for permanent pacemaker placement (0.26 [0.12 to 0.55]) in the MViV cohort, which also lead to overall shorter hospital stays (median difference [95% CI] -7.0 [4.9 to 9.1] days) in this group as well. There were no significant differences in renal failure, stroke rates, total hospital costs, readmission, or 30-, 90-, and 180-day mortality. The authors concluded the MViV offers a short-term advantage over redo SMVR; however, studies with longer follow up are needed to validate these findings.

Whisenant et al. (2020) reported on a prospective cohort study to investigate the SAPIEN 3 transcatheter heart valve (Edwards Lifesciences) as a mitral valve-in-valve (MViV) replacement for an existing bioprosthetic mitral valve that has failed. A total of 1529 patients who underwent transeptal (n = 1326; 86.7%) or transapical (n = 203; 13.3%) MViV implantation were included in the analysis. Of the patients, mitral stenosis was the most common cause of prosthetic valve failure (n= 784; 55.4%), followed by mitral regurgitation (n = 351; 24.8%), and mixed disease (n = 280; 19.8%). Procedural technical success, the primary safety end point, was achieved in 1480 patients (96.8%; 97.1% TS vs 94.6% TA; P = .08). Procedure complications included stroke (n = 10; 0.7%), device embolization (0.3%), LVOT obstruction (0.9%), and cardiac perforation (1.1%). In- hospital deaths attributed to cardiovascular cause were observed in 33 of 1529 patients and occurred more frequently in the transapical access group (4.4% vs. 1.8%; P = .03). The primary efficacy end point, one-year all-cause mortality, was 16.7% and transseptal access was associated with lower rates than transapical (15.8% vs. 21.7%; P = .03). NYHA class, a secondary outcome, also improved to class I or II in 90.3% (n = 1318) of patients. Another secondary outcome, quality of life measured by the Kansas City Cardiomyopathy Questionnaire, improved an average of 29.4 points from baseline.

## National and Specialty Organizations

The **American College of Cardiology** (ACC) and **American Heart Association** (AHA) *2020 Guidelines for the Management of Patients with Valvular Heart Disease* (Otto 2020) does not address TMVI for treatment of MR in a native valve. Preferred treatments of native MR requiring intervention are surgical and transcatheter edge-to-edge repair, and selection between the two depends on various factors. Authors note that in patients with severe symptomatic bioprosthetic valve regurgitation, surgical replacement is preferred unless the member is at high or prohibitive surgical risk, in which case a transcatheter valve-in-valve procedure is reasonable when performed at a Comprehensive Valve Center.

The **National Institute for Health and Care Excellence** (NICE) published an interventional procedures guideline on Transapical *transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis* [IPG706] and included the following recommendations:

- Evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis is adequate and shows some serious but well-recognized complications. Evidence on its efficacy is limited in quality. So, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a

cardiac anesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them.

- The procedure is technically challenging and should only be done in specialized centers, and only by clinical teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures.
- NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. Studies should include details on patient selection, type and size of valve used, functional outcomes, quality of life, patient-reported outcome measures, survival, and complications. Studies should report long-term follow up of clinical outcomes and valve durability.

The **American Association for Thoracic Surgery** (AATS), **The ACC**, The **Society for Cardiovascular Angiography and Interventions** (SCAI), and The **Society for Thoracic Surgeons** (STS) published a joint expert consensus systems of care document outlining operator and institutional recommendations and requirements for transcatheter interventions for treatment of MV disease ([1]Bonow et al. 2020). The guideline underscores the importance of a multidisciplinary team, typically led by interventional cardiology and surgical codirectors, in determining the most appropriate treatment options for each individual patient. Patients are part of the decision-making process and should be well informed of various treatment options, their availability, expected outcomes, and the risks and benefits. The recommendations also note that these procedures should only be performed at centers experienced in both transcatheter and surgical MV intervention.

The **ACC** published the *2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee* ([2]Bonow et al. 2020) to provide guidance on patient evaluation, treatment options, and treatment goals. The consensus statement does not address TMVI other than to note that devices for TMVI are currently under investigation at the time of publication.

## CODING & BILLING INFORMATION

**CPT (Current Procedural Terminology) Codes**

| Code | Description |
|---|---|
| **0483T** | Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed |
| **0484T** | Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (e.g., thoracotomy, transapical) |

**CODING DISCLAIMER.** Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

## APPROVAL HISTORY

**08/14/2024** Policy reviewed. No changes to coverage criteria. Updated references.
**08/09/2023** New policy. Independent Review Organization Peer Review on July 19, 2023, by a practicing, board-certified physician specializing in Cardiology and Interventional Cardiology.

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