Molina Clinical Policy
Transcatheter Mitral Valve Implantation
Policy No. 437

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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

The mitral valve is the bicuspid valve that connects the left atrium of the heart to the left ventricle. **Mitral valve regurgitation** (MR) occurs when blood flows from the left ventricle back through the mitral valve into the left atrium of the heart. 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. Primary (degenerative) MR results from intrinsic abnormalities of the mitral leaflets, chordae tendineae, papillary muscles, or annulus; whereas secondary (functional) MR results from left ventricular remodeling, papillary muscle displacement or annular dilation that prevents normal leaflet coaptation (Otto et al. 2020; Vahanian et al. 2021). MR results in the heart having to work harder to oxygenate the body, which leads to an enlarged left ventricle and can 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. Mitral valve repair may be done via 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, anatomic or functional considerations may limit the feasibility of transcatheter repair, leading those patients to require a mitral valve implant or replacement.

Transcatheter mitral valve implantation (TMVI), also referred to as transcatheter mitral valve replacement, is a minimally invasive intervention aimed at treating 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, over a previously implanted valve (valve-in-valve), or within a surgically implanted annuloplasty ring (valve-in-ring). Less commonly, TMVI may be performed in the setting of severe mitral annular calcification (valve-in-MAC), although this approach carries higher procedural risk and remains limited to select high-risk patients. At this time, evidence for TMVI in native mitral valve disease is primarily derived from early feasibility studies and observational cohorts, with outcomes suggesting potential benefit in carefully selected high-risk patients, however robust randomized or long-term data remain limited (Otto et al. 2020; Vahanian et al. 2022).

Mitral valve-in-valve (MViV) replacement is a transcatheter intervention used to treat dysfunction of a previously implanted bioprosthetic mitral valve. During an MViV procedure, a new bioprosthetic valve is delivered via catheter and deployed within the failing surgical valve to restore function. Transcatheter MViV is generally reserved for patients who are at high or prohibitive risk for open surgical valve replacement (Otto et al. 2020; Vahanian et al. 2021).

Regulatory Status

The SAPIEN M3 Transcatheter Mitral Valve Replacement System, (Edwards Lifesciences) received FDA approval in 2025 for transseptal TMVI in patients with symptomatic moderate to severe or severe MR who are unsuitable for surgery or transcatheter edge-to-edge repair, and for symptomatic mitral valve dysfunction associated with severe mitral annular calcification.

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

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valve who are at high risk or greater for open surgical treatment for transcatheter MVIV replacement. These devices are not approved for TMVI in native mitral valve disease, valve-in-ring, or valve-in-MAC procedures.

The Tendyne Transcatheter Mitral Valve System is a percutaneously delivered mitral valve prostheses that received Breakthrough Device designation in May 2021 and was formally approval on May 23, 2025. It is classified under FDA product code NPU, which corresponds to transcatheter mitral valve prostheses. The FDA approved the Tendyne system for the treatment of symptomatic mitral valve dysfunction associated with severe mitral annular calcification (MAC). Eligible patients may present with moderate-to-severe or severe mitral regurgitation (MR), severe mitral stenosis (MS), or mixed MR/MS, and must be determined unsuitable for surgical mitral valve replacement or transcatheter edge-to-edge repair (TEET) by a multidisciplinary heart team.

COVERAGE POLICY

*Please refer to MCG ORG: S-290 for guidelines on open surgical intervention for mitral valve repair or replacement, and MCG ORG: S-1340 for guidelines on transcatheter mitral valve **repair** (e.g., Mitraclip).*

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 prohibitive 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.

Systematic Reviews and Meta-Analyses

Alperi et al. (2023) conducted a systematic review and included outcomes of 347 patients who underwent TMVI 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 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.

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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 patient, 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 among the different studies. The authors concluded that the Tendyne TMVI system appears to be a promising option for minimally invasive MR intervention.

Non-Randomized Studies, Retrospective Review, and Other Evidence
Sorajja, et al. (2025) reported outcomes of the SUMMIT-MAC study, a prospective, multicenter, single-arm clinical trial enrolling 103 patients with symptomatic severe mitral valve dysfunction associated with severe mitral annular calcification MAC). Patients were considered unsuitable for surgical mitral valve replacement, and nearly all had significant mitral valve regurgitation at baseline. The study population included individuals with moderate-to-severe or severe mitral regurgitation (MR), severe mitral stenosis, or mixed MR/MS. Technical success was achieved in 94.2% of procedures, and 30-day mortality was 6.8%. At 12 months freedom from all -cause mortality and heart failure hospitalization was 60.4% exceeding the prespecified performance. Participants demonstrated meaningful clinical improvement, including better NYHA functional class and improved quality of life as measured by the Kansas City Cardiomyopathy questionnaire. The SUMMIT-MAC study was funded and sponsored by Abbot, the manufacturer of the Tendyne system. This study served as the primary clinical evidence supporting FDA approval of the device for use in patients with severe MAC who are not candidates for surgical mitral valve replacement or transcatheter edge to edge repair. The evidence is limited by the non-randomized, single-arm design and the highly selective population of patients with severe MAC who were not candidates for surgery.

Guerrero et al (2025) conducted a prospective, multi-enter, single arm pivotal trial evaluating percutaneous transseptal transcatheter mitral valve implantation (TMVI) using the SAPIEN M3 system in adults with symptomatic moderate to severe or severe mitral regurgitation who were unsuitable for surgery or transcatheter edge-to-edge repair (TEER). Of 1,171 patients screened , 299 were treated across 56 centers. Device implantation was completed in 287 (96%), with no intraprocedural deaths, conversions to surgery, or clinically significant left ventricular outflow tract obstruction. The primary endpoint, a composite of all-cause mortality or heart failure rehospitalization at 1 year was 25.2%, significantly lower than the prespecified performance goal of 45%. At 1 year, all -cause mortality was 13.9% and heart failure rehospitalization was 16.7%. Mitral regurgitation was reduced to mild or less in 96% of evaluable patients, with associated improvements in NYHA class, KCCQ-OS scores , and favorable ventricular remodeling. Major adverse events included disabling stroke (3.9%), clinically significant valve thrombosis (7%), and mitral valve reintervention occurred in 6.4% of patients. Limitations include the single-arm design without a randomized comparator, short follow -up duration, potential survival bias, performance at highly experienced centers, and a high screen-failure rate limiting generalizability. The absence of a control group also introduces potential for placebo effects, patient-selection bias, and assessment bias. Edwards Lifesciences sponsored the study.

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 ($P = 0.75$), 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 ($P < 0.05$). 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 TMVI 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%)

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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 TMVI, 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 TMVI with the Tendyne Mitral Valve System (Abbott) 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 patients 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)

Current evidence for transcatheter mitral valve-in-valve (MViV) replacement is limited to retrospective studies, registry analyses, and systematic reviews. While early findings suggest favorable short-term outcomes and reduced procedural risk in high-surgical-risk patients, long-term safety and durability data remain limited.

Systematic Reviews and Meta-Analyses

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 TMVI 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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

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%

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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 Guideline for the Management of Patients with Valvular Heart Disease* (Otto et al. 2020) predates the emergence of contemporary TMVI technologies and the pivotal clinical trials that supported recent FDA approvals of TMVI devices. Consequently, the guideline does not provide specific recommendations regarding TMVI for native mitral valve disease. For patients with primary mitral regurgitation (MR) requiring intervention, the guideline emphasized surgical mitral valve repair as the preferred treatment for severe primary MR when feasible, and mitral transcatheter edge-to-edge repair (TEER) as beneficial for patients with severe symptomatic primary MR who are at high or prohibitive surgical risk, as well as for a select subset of patients with secondary MR who remain symptomatic despite guideline-directed medical therapy for heart failure. The authors further note that in patients with severe symptomatic prosthetic bioprosthetic valve dysfunction, surgical replacement is preferred unless the patient 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.

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The **American Association for Thoracic Surgery** (AATS), **American College of Cardiology (**ACC), **Society for Cardiovascular Angiography and Interventions** (SCAI), and **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 consensus document underscores the importance of a multidisciplinary team, typically led by interventional cardiology and surgical codirectors, in determining the most appropriate treatment strategy 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 therapies and with the infrastructure necessary to support comprehensive valve care.

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 for native mitral valve disease and does not provide specific recommendations regarding TMVI. At the time of publication, transcatheter mitral valve replacement technologies were investigational and were noted as being under clinical evaluation. Consequently, the document focuses on surgical intervention and transcatheter edge-to-edge repair (TEER) rather than TMVI.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

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)

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APPROVAL HISTORY

08/12/2026	Policy reviewed. No changes to coverage criteria.
08/13/2025	Policy reviewed. No changes to coverage criteria.
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.

REFERENCES

1. Ahmed A, Aziz TAA, AlAsaad MMR, et al. Transcatheter mitral valve implantation with Tendyne System ten years since the first in-human implant A systematic review. J Cardiothorac Surg. 2023 Nov 10;18(1):315. doi: 10.1186/s13019-023-02446-4. PMID: 37950282; PMCID: PMC10638771.
2. Alperi A, Avanzas P, Leon V, et al. Current status of transcatheter mitral valve replacement: Systematic review and meta-analysis. Front Cardiovasc Med. 2023 May 10; 10:1130212. doi: 10.3389/fcvm.2023.1130212. PMID: 37234369; PMCID: PMC10206247.
3. Bapat V, Rajagopal V, Meduri C, et al. Early experience with new transcatheter mitral valve replacement. J Am Coll Cardiol. 2018 Jan 2;71(1):12-21. doi: 10.1016/j.jacc.2017.10.061. Epub 2017 Nov 16. PMID: 29102689.
4. [1]Bonow RO, O'Gara PT, Adams DH, et al. 2019 AATS/ACC/SCAI/STS Expert consensus systems of care document: Operator and institutional recommendations and requirements for transcatheter mitral valve intervention: A joint report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and The Society of Thoracic Surgeons. J Am Coll Cardiol. 2020 Jul 7;76(1):96-117. doi: 10.1016/j.jacc.2019.12.002. Epub 2019 Dec 16. Erratum in: J Am Coll Cardiol. 2020 Jul 7;76(1):130. PMID: 31857196.

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5. [2]Bonow RO, O'Gara PT, Adams DH, et al. 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. J Am Coll Cardiol. 2020 May 5;75(17):2236-2270. doi: 10.1016/j.jacc.2020.02.005. Epub 2020 Feb 14. Erratum in: J Am Coll Cardiol. 2020 Jun 16;75(23):3000. PMID: 32068084
6. Hungerford SL, Bart NK, Song N, et al. Transcatheter mitral valve edge-to-edge repair versus transapical mitral valve replacement in patients with LV dysfunction. JACC Cardiovasc Imaging. 2022 Aug;15(8):1514-1516. doi: 10.1016/j.jcmg.2022.02.017. PMID: 35926910.
7. Muller DWM, Farivar RS, Jansz P, et al. Transcatheter mitral valve replacement for patients with symptomatic mitral regurgitation: A global feasibility trial. J Am Coll Cardiol. 2017 Jan 31;69(4):381-391. doi: 10.1016/j.jacc.2016.10.068. Epub 2016 Dec 28. Erratum in: J Am Coll Cardiol. 2017 Mar 7;69(9):1213. PMID: 28040318.
8. Muller DWM, Sorajja P, Duncan A, et al. 2-Year outcomes of transcatheter mitral valve replacement in patients with severe symptomatic mitral regurgitation. J Am Coll Cardiol. 2021 Nov 9;78(19):1847-1859. doi: 10.1016/j.jacc.2021.08.060. PMID: 34736561.
9. National Institute for Health and Care Excellence. Transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. Interventional procedures guidance [IPG706]. Published: 22 September 2021. Accessed July 22, 2026. https://www.nice.org.uk/guidance.
10. Otto CM, Nishimura RA, Bonow RO. 2020 ACC/AHA Guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021 Feb 2;143(5): e72-e227. doi: 10.1161/CIR.0000000000000923. Epub 2020 Dec 17. Erratum in: Circulation. 2021 Feb 2;143(5): e229. PMID: 33332150.
11. Sorajja P, Moat N, Badhwar V, et al. Initial Feasibility study of a new transcatheter mitral prosthesis: The first 100 patients. J Am Coll Cardiol. 2019 Mar 26;73(11):1250-1260. doi: 10.1016/j.jacc.2018.12.066. PMID: 30898200.
12. Sorajja P, Thourani VH, Rogers JH, Bethea B, Guerrero ME, Lim DS, et al. Transcatheter mitral valve replacement for severe mitral annular calcification: Primary outcomes from the SUMMIT-MAC Study. J Am Coll Cardiol. 2026 Jun 16;87(23):3243-3256. doi: 10.1016/j.jacc.2025.10.025. Epub 2025 Oct 27. PMID: 41194751.
13. United States Food and Drug Administration (FDA). Premarket Approval Database. Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System. Product Code: NPU. PMA Number: P140031. Accessed July 2, 202. https://www.accessdata.fda.gov
14. United States Food and Drug Administration (FDA). Premarket Approval Database/ Tendyne Transcatheter Mitral Valve System. Product Code: NPU. PMA Number P240042. Accessed August 3, 2026. https://www.accessdata.fda.gov
15. United States Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): SAPIEN M3 Transcatheter Mitral Valve Replacement System. Premarket Approval (PMA) P250019 [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 2025 Dec 22 Accessed July,2, 2026. https://www.accessdata.fda.gov/cdrh_docs/pdf25/P250019B.pdf [accessdata.fda.gov]
16. Vanahain A, Beyersdorf F, Praz F, Milojevic M, Baldus S, et al. ESC/EACTS Scientific Document Group. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022 Feb 12;43(7):561-632. doi: 10.1093/eurheartj/ehab395. Erratum in: Eur Heart J. 2022 Jun 1;43(21):2022. doi: 10.1093/eurheartj/ehac051. PMID: 34453165.
17. Whisenant B, Kapadia SR, Eleid MF, et al. One-year outcomes of mitral valve-in-valve using the SAPIEN 3 transcatheter heart valve. JAMA Cardiol. 2020 Nov 1;5(11):1245-1252. doi: 10.1001/jamacardio.2020.2974. PMID: 32745164; PMCID: PMC7391176.
18. Zhou J, Li Y, Chen Z, Zhang H. Transcatheter mitral valve replacement versus redo surgery for mitral prosthesis failure: A systematic review and meta-analysis. Front Cardiovasc Med. 2023 Jan 18; 9:1058576. doi: 10.3389/fcvm.2022.1058576. PMID: 36741847; PMCID: PMC9889358.
19. Zogg CK, Hirji SA, Percy ED, et al. Comparison of post discharge outcomes between valve-in-valve transcatheter mitral valve replacement and reoperative surgical mitral valve replacement. Am J Cardiol. 2023 Aug 15; 201:200-210. doi: 10.1016/j.amjcard.2023.01.039. PMID: 37385175.

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