Cohere Medical Policy - Transcatheter Mitral Valve Repair

Clinical Policy for Medical Necessity Review

Version: 2
Cohere Health UMC Approval Date: July 10, 2025
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Revision: Not Applicable
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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

Cohere Health, Inc. ("**Cohere**") has published these clinical guidelines to determine the medical necessity of services (the "**Guidelines**") for informational purposes only, and solely for use by Cohere's authorized "**End Users**". These Guidelines (and any attachments or linked third-party content) are not intended to be a substitute for medical advice, diagnosis, or treatment directed by an appropriately licensed healthcare professional. These Guidelines are not in any way intended to support clinical decision-making of any kind; their sole purpose and intended use is to summarize certain criteria Cohere may use when reviewing the medical necessity of any service requests submitted to Cohere by End Users. Always seek the advice of a qualified healthcare professional regarding any medical questions, treatment decisions, or other clinical guidance. The Guidelines, including any attachments or linked content, are subject to change at any time without notice.

Other Notices:

Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Transcatheter Mitral Valve Repair
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Transcatheter Mitral Valve Repair

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
  - The medical necessity of each individual request
  - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
  - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Percutaneous or transcatheter mitral valve repair (TMVR), also defined as mitral valve transcatheter edge-to-edge repair (TEER), is a minimally invasive procedure not requiring open heart surgery for the treatment of primary (degenerative) or secondary (functional) mitral regurgitation. It is performed by accessing a large blood vessel in either the groin or chest with a catheter, then deploying a device inside the mitral valve, often a "clip," which alters the anatomy of the mitral valve leaflets. TMVR is indicated for symptomatic patients with moderate to severe primary mitral regurgitation (MR) equal or greater than Grade III per American Society of Echocardiography criteria,[1,10] and for patients with high or prohibitive surgical risk for open surgical valve repair.[1,10]

Medical Necessity Criteria

Indications

Transcatheter Mitral Valve Repair is considered appropriate if **ANY** of the following is **TRUE**[4,6]:

- TMVR for primary (degenerative [i.e., not rheumatic]) MR is indicated by **ALL** of the following[4,6]:
  - Moderate-Severe or Severe MR; **AND**
  - **ANY** of the following:
    - Left ventricular (LV) systolic dysfunction (left ventricular ejection fraction [LVEF] less than or equal to 60% or ESD of at least 40mm)[4]; **OR**
    - Significant symptoms (NYHA class III or IV) regardless of LV function **AND**
  - High or prohibitive surgical risk as defined by **ANY** of the following[4]:
    - Society of Thoracic Surgeons (STS) PROM equal to or greater than 8% for individuals deemed likely to undergo mitral valve replacement[15]; **OR**
    - STS PROM equal to or greater than 6% for individuals deemed likely to undergo mitral valve repair.[15]
  - Life expectancy of at least 1 year[4]; **AND**
  - Mitral valve anatomy is favorable for transcatheter repair [4]; **OR**

- TEER for severe secondary MR with **ALL** of the following[4,6]:
  - Left ventricular end-systolic diameter (LVESD) less than or equal to 70 mm[6]; **AND**
  - LVEF greater than or equal to 20% and less than or equal to 50%[6]; **AND**
  - Persistent symptoms while on optimal medical therapy (including cardiac resynchronization, if indicated)[4,6]; **AND**
  - Pulmonary artery systolic pressure less than or equal to 70 mm Hg[4]; **OR**
- Percutaneous transcatheter mitral valve-in-valve implantation is indicated for a patient with **ALL** of the following[11]:
  - Symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring[11]; **AND**
  - High or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality equal or greater than 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).[11]

Non-Indications

Transcatheter Mitral Valve Repair is not considered appropriate if **ANY** of the following is **TRUE**[4,6,11]:

- Active endocarditis of the mitral valve[6]; **OR**
- Another cardiac surgery is planned where surgical mitral valvuloplasty can be effectively performed[11]; **OR**
- Presence of intracardiac or venous (inferior vena cava or femoral vein) thrombosis is present[6]; **OR**
- Extensive chordal fusion or calcification[4]; **OR**
- Mitral valve insufficiency is due to a congenital cleft (transitional atrioventricular canal)[4]; **OR**
- Papillary muscle rupture[4]; **OR**
- The patient cannot tolerate anticoagulation or antiplatelet therapy post-procedure[4,6]; **OR**
- Rheumatic mitral valve disease[6]; **OR**
- Mixed valve disease(i.e. - concomitant aortic or tricuspid dysfunction)[4]; **OR**
- Aortic aneurysm or other aortopathy wherein surgical mitral valve repair would be preferable[16]; **OR**
- Untreatable hypersensitivity or contraindication to contrast media or nitinol alloys (nickel and titanium)[6]; **OR**

- The patient has significant annuloplasty ring dehiscence.[11]

Definitions

New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994):

- **I:** No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
- **II:** Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
- **III:** Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- **IV:** Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

STS PROM: Society of Thoracic Surgery predicted risk of mortality.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33418	Transcatheter mitral valve repair with initial prosthetic valve by percutaneous approach
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)
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed.

Medical Evidence

Transcatheter mitral valve-in-valve is an innovative procedure authorized by the United States Food and Drug Administration (FDA) for high-risk individuals with a malfunctioning (stenosis, MR, or combined) surgical bioprosthetic mitral valve or a native mitral valve with an annuloplasty ring deemed by a heart team to pose high or greater risk for open surgical intervention.[11] Goel et al. (2024) performed an extensive cohort analysis of 4,243 patients from the Transcatheter Valve Therapies registry (STS/American College of Cardiology) undergoing transseptal SAPIEN 3/SAPIEN 3 Ultra transcatheter mitral valve-in-valve procedures before and after FDA approval (2015–2022). Most patients were classified as high surgical risk; however, 30-day and 1-year mortality rates were acceptable, with a significant improvement in symptoms and quality of life.[13] Malaisrie et al. (2024), in a prospective, single-arm, multicenter study in intermediate-risk patients, found that mitral valve-in-valve with a balloon-expandable valve was associated with no mortality, no strokes, low complication rates, symptom improvements, and patient-reported quality of life improvement in a 1-year follow-up.[12] In a large multicenter study that included 5,971 patients, Eleid et al. (2025) found that three-year mortality was lowest in patients with low STS risk scores and elective procedures. They reason that it is crucial to identify patients who may benefit from mitral valve-in-valve early. Also, reintervention rates were low at three years regardless of STS risk scores.[14]

McCarthy et al. (2023) report on the REPAIR-MR (Primary Mitral Regurgitation) clinical trial, which began in July 2020. The trial is a prospective, randomized, parallel-controlled, open-label multicenter, noninferiority study aimed at evaluating the efficacy and safety of transcatheter edge-to-edge repair using the MitraClip compared to surgical (open-chest) mitral valve repair in patients diagnosed with severe primary MR (ClinicalTrials.gov ID NCT04198870). Participants must meet moderate surgical risk criteria and must have a diagnosis of severe MR and indications for surgery due to symptoms (NYHA class II-IV) - patients without symptoms will also be included if certain criteria is met (e.g., left ventricular ejection fraction less than or equal to 60%, pulmonary artery systolic pressure greater than 50 mm Hg, or left ventricular end-systolic diameter greater than or equal to 40 mm).

All participants are 75 years of age or older, or, less than 75 years of age with a Society of Thoracic Surgeons Predicted Risk Of Mortality score of greater than or equal to 2% for mitral repair (or Society of Thoracic Surgeons Replacement Score of greater than or equal to 4%), or having comorbidities increasing surgical risk. The trial aims to randomize 500 eligible subjects in a 1:1 ratio between the MitraClip device and surgical mitral valve repair (control group) with two co-primary endpoints evaluated at 2 years and follow-up continuing for 10 years post-enrollment.[7]

Kong et al. (2023) conducted the COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation) trial (ClinicalTrials.gov ID NCT01626079). The trial explored the occurrence and consequences of deteriorating kidney function following TEER of the mitral valve in individuals diagnosed with heart failure (HF). A total of 614 patients with diagnosed HF and severe secondary mitral regurgitation (SMR) underwent randomization to receive TEER using the MitraClip in addition to guideline-directed medical therapy (GDMT), compared to those receiving GDMT alone. In patients with HF alongside severe SMR, the occurrence of worsening renal function within 30 days was not found to be higher following TEER compared to standard GDMT alone. Despite its association with increased mortality over 2 years, worsening renal function did not diminish the efficacy of TEER in reducing mortality and HF-related hospitalizations when compared to GDMT alone.[8]

Giustino et al. (2020) performed a randomized controlled trial to compare MitraClip implantation and GDMT outcomes in patients diagnosed with SMR. Patients were stratified by their initial functional status as determined by the NYHA functional classification. The COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation) trial (ClinicalTrials.gov ID NCT01626079) included patients with HF and either moderate to severe or severe SMR who continued to experience symptoms despite receiving the maximum tolerated GDMT. A total of 613 patients were randomized - 240 (39.2%) were in the NYHA functional class II, 322 (52.5%) were in NYHA functional class III, and 51 (8.3%) were in ambulatory NYHA functional class IV. They found that the benefits of MitraClip were consistent with the NYHA functional class assessment and that

such functional assessment provides prognostic utility in patients with HF and moderate to severe or severe SMR.[9]

The FDA approved MitraClip to improve mitral insufficiency due to primary degenerative mitral valve abnormalities or functional mitral valve insufficiency due to diminished left ventricular function.[1] Other types of repair include chordal repair (NeoChord, Harpoon), edge-to-edge repair (MitraClip, PASCAL), indirect annuloplasty (ARTO, Carillon, Mitral Loop Cerclage), and direct annuloplasty (AccuCinch, Cardioband, Millipede, Mitralign).[2-3] The MitraClip procedure avoids the need for additional extensive surgical valve repair (or replacement) with decreased morbidity and mortality.

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Policy Revision History/Information

Original Date: April 5, 2024		
Review History		
Version 2	07/10/2025	Annual review. Deleted indications for patient enrollment in experimental studies (not covered by any payor policy examined). Changed indication: “Moderate to severe mitral regurgitation (MR)” to “Moderate-Severe or Severe MR.” Added indication, “Percutaneous transcatheter mitral valve-in-valve implantation is indicated for patients with ALL of the following: Symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring; AND High or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality equal or higher than 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).” Expanded indication: “High or prohibitive surgical risk” to “High or prohibitive surgical risk as defined by ANY of the

		following: 1) STS PROM equal to or greater than 8% for individuals deemed likely to undergo mitral valve replacement15; OR STS PROM equal to or greater than 6% for individuals deemed likely to undergo mitral valve repair." Added non-indication: "The patient has significant annuloplasty ring dehiscence." Added non-indication: "Aortic aneurysm or other aortopathy wherein surgical mitral valve repair would be preferable." Added non-indication: "The patient has significant annuloplasty ring dehiscence." Added CPT code 33419. Added CPT code 0483T. Literature review: The Medical Evidence section (including references) for the FDA-approved Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve systems was updated.