Transcatheter Mitral Valve Repair - Single Service

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: April 5, 2024

Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Transcatheter Mitral Valve Repair (Single Service)

Literature review current through: 4/5/2024
Document last updated: 4/5/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

Table of Contents

Medical Necessity Criteria

Service: Transcatheter Mitral Valve Repair

General Guidelines

- **Units, Frequency, & Duration:** Single request.
- **Criteria for Subsequent Requests:** Revision of mitral valve repair is rarely required for subsequent valve leaks or dysfunction.
- **Recommended Clinical Approach:** Transcatheter mitral valve repair (TMVR) is indicated for symptomatic patients with moderate to severe primary mitral regurgitation (MR) (3-4+) who have NYHA Class III-IV heart failure symptoms and are considered high or prohibitive surgical risk for open surgical valve repair. Primary mitral valve disease includes degenerative valve disease, mitral valve prolapse, and flail mitral leaflet but does not include MR due to coronary artery disease (CAD) or prior myocardial infarction (MI). The United States Food and Drug Administration (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. Transesophageal echocardiography (TEE) is routinely performed before the MitraClip procedure to confirm if the patient has the appropriate anatomy for repair.[4] The patient requires anticoagulation with heparin during the procedure and six months of antiplatelet therapy afterward. Hospitalization is usually only required overnight. Risks of TMVR include bleeding from the access site, tamponade during the septal puncture, and the rare occurrence of device embolization or partial displacement, usually requiring surgery.
- **Exclusions:** Active endocarditis of the mitral valve; extensive chordal fusion or calcification; the mitral valve is felt to be unsuitable for percutaneous, edge-to-edge repair based on the pre-procedural TEE or TTE; papillary muscle rupture; presence of thrombus in the femoral vein, inferior vena cava, or within a cardiac chamber (specifically the left atrium); rheumatic or other cause of mitral stenosis; or the patient cannot tolerate anticoagulation or antiplatelet therapy post-procedure.

Medical Necessity Criteria

Indications

- ➔ **Transcatheter Mitral Valve Repair** is considered appropriate if **ALL** of the following are **TRUE**[1,4-6]:
  - ◆ The patient is enrolled in **ANY** of the following:
    - An approved Clinical Study as listed on the CMS Coverage with Evidence Development (CED) website (https://www.cms.gov/medicare/coverage/evidence/edge-to-edge-repair-teer); **OR**
    - Facility enrollment in the STS/ACC TVT Registry Mitral Module (TMVR) (https://www.ncdr.com/WebNCDR/tvt/publicpage/participantdirectory); **AND**
  - ◆ **ANY** of the following:
    - Transcatheter edge-to-edge repair (TEER) for primary (degenerative) mitral regurgitation (MR) is indicated by **ALL** of the following:
      - Significant symptoms (NYHA class III or IV) with primary moderate to severe mitral regurgitation (MR); **AND**
      - High or prohibitive surgical risk; **AND**
      - Life expectancy of at least 1 year; **AND**
      - Mitral valve anatomy is favorable for repair procedure; **OR**
    - The patient has chronic moderate to severe secondary mitral regurgitation (MR) related to left ventricle (LV) systolic dysfunction with LVEF (left ventricular ejection fraction) less than 50% with **ALL** of the following:
      - LVESD less than or equal to 70 mm; **AND**
      - LVEF greater than or equal to 20% and less than or equal to 50%; **AND**
      - Persistent symptoms (NYHA class II, III, or IV) while on optimal medical therapy (including cardiac resynchronization, if indicated); **AND**
      - Pulmonary artery systolic pressure less than or equal to 70 mm Hg.

Non-Indications

- ➔ **Transcatheter Mitral Valve Repair** is not considered appropriate if **ANY** of the following is **TRUE**[1,4-6]:
  - ◆ Active endocarditis of the mitral valve; **OR**

- Another cardiac surgery is planned where surgical mitral valvuloplasty can be effectively performed; **OR**
- Presence of intracardiac or venous (IVC or femoral vein) thrombosis is present; **OR**
- Extensive chordal fusion or calcification; **OR**
- Mitral valve insufficiency is due to congenital cleft (transitional AV canal); **OR**
- Mitral valve insufficiency is due to damage from infective endocarditis; **OR**
- Papillary muscle rupture; **OR**
- The patient cannot tolerate anticoagulation or antiplatelet therapy post-procedure; **OR**
- The patient requires heart surgery for another form of cardiac disease (e.g., coronary artery disease [CAD]) requiring coronary artery bypass surgery (CABG); **OR**
- Presence of thrombus in **ANY** of the following:
  - Femoral vein; **OR**
  - Inferior vena cava; **OR**
  - Within a cardiac chamber, especially the left atrium; **OR**
- Rheumatic mitral valve disease; **OR**
- Severe, untreated aortic stenosis; **OR**
- Untreatable hypersensitivity or contraindication to contrast media or nitinol alloys (nickel and titanium).

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
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

Medical Evidence

McCarthy et al. (2023) report on the REPAIR MR 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 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 (New York Heart Association [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 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 transcatheter edge-to-edge repair (TEER) of the mitral valve in individuals diagnosed with heart failure (HF). A total of 614 patients with diagnosed HF and severe 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 a 2-year period, WRF 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 control trial (RCT) to compare the outcomes between MitraClip implantation and GDMT in patients diagnosed with secondary mitral regurgitation (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.[9]

References

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