KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Transcatheter Mitral Valve Repair (TMVR)

- MitraClip

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Decision Memo	Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R)

For Non-Medicare Members

Transcatheter mitral valve repair using a device approved by the U.S. Food and Drug Administration for use in mitral valve repair may be considered medically necessary for patients with symptomatic, primary mitral regurgitation who are considered at prohibitive risk for open surgery.

Prohibitive risk for open mitral valve repair surgery may be determined based on the following:

- The documented presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater

AND/OR

- The documented presence of a logistic EuroSCORE of 20% or greater

Transcatheter mitral valve repair with a device approved by the U.S. Food and Drug Administration may be considered medically necessary for patients with heart failure and moderate-to-severe or severe* symptomatic secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy**.

* Moderate to severe or severe MR may be determined by:

- Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography
- New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies.

**Optimal guideline directed medical therapy (GDMT) - see reference below:
https://www.jacc.org/doi/10.1016/j.jacc.2020.11.022

Transcatheter mitral valve repair is considered investigational in all other situations.

Reference

Maddox, T. M., Januzzi, J. L., Allen, L. A., Breathett, K., Butler, J., Davis, L. L., Fonarow, G. C., Ibrahim, N. E., Lindenfeld, J. A., Masoudi, F. A., Motiwala, S. R., Oliveros, E., Patterson, J. H., Walsh, M. N., Wasserman, A., Yancy, C. W., Youmans, Q. R., J.L., J., Al., E., … F.J., de A. (2021, February 1). *2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: Answers to 10 pivotal issues about heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee*. Journal of

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the American College of Cardiology. Retrieved February 11, 2022, from https://www.jacc.org/doi/10.1016/j.jacc.2020.11.022

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Name of the Food and Drug Administration (FDA) approved device to be used

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Transcatheter mitral valve repair (TMVR) is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation (MR); currently MitraClip® is the only one with Food and Drug Administration (FDA) approval.

U.S. FDA–MitraClip Clip Delivery System (MitraClip CDS) (Abbott Vascular, Menlo Park, CA): The MitraClip CDS received FDA approval through the PMA process on October 24, 2013. It is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. The device is contraindicated in patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen, and those with active endocarditis of the mitral valve, rheumatic mitral valve disease, or evidence of intracardiac, inferior vena cava or femoral venous thrombus.

The MitraClip system consists of implant catheters and the MitraClip device, a permanent implant that attaches to the mitral valve leaflets. The procedure results in a double opening of the mitral valve that allows greater closure and reduces mitral regurgitation.

Medical Technology Assessment Committee (MTAC)

MitraClip System

BACKGROUND

Mitral regurgitation (MR) is the second most common valvular heart disease after aortic stenosis. The natural history of severe MR without surgical intervention is poor, leading to worsening LV failure, pulmonary hypertension, atrial fibrillation and death. It is reported that without surgical treatment, patients with severe symptomatic MR have an annual mortality rate of 5% per year, and as high as 60% at 5 years if associated with significant heart failure (Mauri 2010).

MR is broadly categorized as primary or secondary. Primary MR, also known as degenerative MR (DMR), describes an abnormality of the leaflets varying from a prolapse of an isolated segment in a normally shaped valve, to multiple segment prolapse involving one or both leaflets in a valve with significant excessive tissue and large annular size. Secondary MR, also known as functional MR (FMR), is secondary to left ventricular (LV) remodeling with structurally preserved mitral leaflets. Surgical mitral valve repair/replacement remains the gold standard for the treatment of symptomatic MR, though it has some controversy in FMR due to the lack of clear survival benefit and high recurrence rates of MR at 1 year after surgery. Current guidelines recommend MV surgery in patients with moderate to severe (grade 3+) or severe (4+) MR associated with symptoms or evidence of LV dysfunction. Surgical repair of the valve before the onset of limiting symptoms or LV dysfunction can restore normal life expectancy and quality of life. The conventional surgery for MV repair/replacement is an open-heart surgery performed under cardiopulmonary bypass. It is reported that as many as 49% of patients in need of MR repair or replacement are considered at high surgical risk and are denied surgical treatment due to their age, advanced LV systolic dysfunction, previous bypass surgeries, or significant comorbidities. Patients who do not qualify for surgical correction of the MV are treated with medical therapy alone, which may reduce their symptoms, but does not stop the disease progression (Estevez-Loureiro 2013 Mauri 2013, Vakil 2013, Wan 2013, Munkholm-Larsen 2014). In the past 15 years, percutaneous valve therapy has been advancing rapidly especially for the aortic and pulmonic valve replacement. This development of percutaneous mitral valve (MV) therapies has been slower due to the anatomy of the MV and its relationship with the left ventricle. A number of devices for MV repair have been introduced as potential alternatives to open surgical procedures; many have failed, and more

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are at different stages of investigation. Percutaneous or minimally invasive repair systems target the MV leaflets, annulus or the left ventricle, e.g. the Neochord DS1000, the Carillon Mitral Contour System, and the MitraClip system. The latter is the only one in clinical use across the United States and Europe (Munkholm-Larsen 2014, Rana 2015).
The concept of the MitraClip system (Abbott Vascular, Menlo Park, California) is based on the edge-to-edge repair technique developed by Alfieri and colleagues in the early 2000s. This technique involves suturing of the middle scallops of the anterior and posterior MV leaflets resulting in a double orifice valve. The MitraClip is a single-sized system that consists of a 4mm wide cobalt chromium clip with two foldable arms designed to grasp the moving leaflets; a 10Fr delivery catheter, with a radiopaque distal tip, and a 24-Fr steerable sleeve. The procedure is performed in the cardiac catheterization laboratory under general anesthesia, anticoagulation, and fluoroscopic and transesophageal echocardiographic guidance. The MV is accessed via the femoral vein and right atrium then to the left atrium via a transseptal puncture. The system is advanced into the left ventricle and the clip is deployed for permanent approximation of the anterior and posterior MV leaflets creating a double orifice MV during diastole. Reduction in MR is assessed by echocardiography during the procedure, and more than one clip may be used at the operator's discretion. At the end, the catheters are withdrawn, and the patient treated with aspirin for 6 months and clopidogrel for 30 days (Wan 2013, Vakil 2013, Munkholm-Larsen 2014, Rana 2015).
Several anatomic parameters must be satisfied to determine the appropriate patients for the procedure. These differ for patients with DMR and FMR. Anatomical criteria for DMV include flail width and gap size, prolapse location, length of posterior MV leaflet (PMVL) and MV orifice size. The criteria for MV anatomy include coaptation depth and length, the MV orifice size, and the MV transvalvular gradient. Lesions ideal for MitraClip lie within the central portion at the coaptation line, have a flail width <15 mm with a flail gap <10mm, and as the MitraClip reduces the MV orifice, the preimplantation area should be >40 mm^2. A hypoplastic posterior leaflet is a contraindication, and heavy calcification, fibrosis, or deep clefts within the clip grasping area have potential for clip implantation failure. The percutaneous MV repair with the MitraClip system depends heavily on echo-imaging during the implantation and early on for assessing the suitability for clip placement, which is the cornerstone for the success of the technique. It has been reported that some technical aspects of the MitraClip implantation remain operator dependent and have not been fully standardized, and that the correct strategy for patients with complex valve anatomy remains controversial (Paranskaya 2013, Rana 2015).
The MitraClip treatment of MR is less invasive than surgery but may be associated with potentially life-threatening complications. The incidence of the reported procedure-related complications is generally low and varies considerably between studies. These included bleeding that require >2 units of blood transfusion (the most common), vascular access site complications, transseptal puncture
(which may also cause to aortic root needle puncture), partial clip detachment, clip attachment to a single leaflet, leaflet injury or laceration, mitral valve stenosis, mitral valve injury, acute heart failure, and stroke (Bakker 2013).
According to the device manufacturer and the FDA (approval in October, 2013), MitraClip implantation is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral valve (degenerative MR), who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. It is contraindicated in patients who cannot tolerate anticoagulation required during the procedure or antiplatelet therapy required after the procedure; in patients with active MV endocarditis; rheumatic MV disease; and in patients with evidence of femoral venous, inferior vena cava, or intracardiac thrombus. (http://mitraclip.com, and FDA webpage accessed July 17, 2015)

08/17/2015: MTAC REVIEW
MitraClip System
Evidence Conclusion:
There is evidence from EVEREST II RCT with 4 years of follow-up, that the implantation of MitraClip is less effective than surgery in improving the mitral regurgitation in patients with moderate or severe symptomatic mitral valve regurgitation who are suitable candidates for conventional surgery. The is low quality, but consistent evidence from observational studies and registries that implantation of MitraClip in patients with symptomatic moderate or severe symptomatic mitral valve regurgitation who are at high surgical risk, is feasible and is associated with clinical improvement and relatively low risk of major adverse events. However, there is no evidence to date to determine the durability of clinical improvements and optimal criteria for patient selection. There is insufficient evidence to determine the outcomes of MitraClip device by etiology of mitral regurgitation (FMR or DMR). Two ongoing RCTs (COPAT in the US and RESHAPE-HF trial in Europe) are comparing MitraClip implantation versus medical therapy in high surgical risk patients, and their results may provide more evidence on the relative safety and efficacy of implanting the device in these patients.
Articles: The literature search revealed EVEREST I feasibility trial; EVEREST II randomized controlled with four publications (the last of which reported on 4-years follow-up outcomes); 4 other nonrandomized
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comparative studies with retrospective controls including EVEREST II High Risk Study (HRS); a number of uncontrolled studies; a meta-analysis that pooled the results of the RCT and comparative studies; 3 systematic reviews (2 on the safety and efficacy of MitraClip in patients at high surgical risk, and one for patients with severe MR); and a number of industry-supported or industry-independent registries (REALISM, ACCESS Europe, Everest High-risk register) TRAMI German registry, and GRASP registry),The EVEREST II RCT, the EVEREST II HRS, and the meta-analysis that examined the safety and efficacy of MitraClip for patients at high surgical risk were selected for critical appraisal. Feldman T, Foster E, Glower DD, et al for the EVEREST II Investigators. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med*. 2011 Apr 14; 364(15):1395-406. See Evidence Table 1. Mauri L, Garg P, Massaro JM, Foster E, et al. The EVEREST II Trial: design and rationale for a randomized study of the evalve mitraclip system compared with mitral valve surgery for mitral regurgitation. *Am Heart J*. 2010 Jul; 160 (1):23-29. See Evidence Table 1. Philip F, Athappan G, Tuzcu EM, et al. MitraClip for severe symptomatic mitral regurgitation in patients at high surgical risk: a comprehensive systematic review. *Catheter Cardiovasc Interv*. 2014 Oct; 84(4):581-590. See Evidence Table 3. Mauri L, Foster E, Glower DD, et al. for the EVEREST II Investigators. 4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation. *J Am Coll Cardiol*. 2013 Jul 23; 62(4):317-328. See Evidence Table 1. Wan B, Rahnavardi M, Tian DH, et al. A meta-analysis of MitraClip system versus surgery for treatment of severe mitral regurgitation. *Ann Cardiothorac Surg.* 2013. Nov; 2(6):683-692. Whitlow Pl, Feldman T, Pederson WS et al on behalf of the EVEREST II Investigators. Acute and 12-Month Results with Catheter-Based Mitral Valve Leaflet Repair: The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. *J Am Coll Cardiol*. 2012. January; 59:130–139. See Evidence Table 2.

The use of the MitraClip System does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
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)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/13/2015	09/01/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC] 02/01/2022[MPC], 02/07/2023[MPC], 04/02/2024[MPC], 04/01/2025[MPC]	01/05/2021

[MPC] Medical Policy Committee

Revision History	Description
01/05/2021	MPC approved to adopt changes to criteria to include symptomatic secondary mitral regurgitation and high-risk score for traditional surgery. Requires 60-day notice, effective date 06/01/2021.

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