

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

Effective Date:	11/1/2024
------------------------	------------------

[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)
[APPENDIX](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

Transcatheter mitral valve repair with 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 (see Policy Guidelines section).

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 (see Policy Guidelines).

Transcatheter mitral valve replacement of a degenerated bio-prosthetic valve (valve-in-valve) with a device approved by U.S. Food and Drug Administration may be considered **medically necessary** when **ALL** of the following criteria are met:

- The individual has a failed (i.e., stenosed, insufficient, and/or combined) previous surgical bio-prosthetic mitral valve; **and**
- At the discretion of the Heart Team specialists, the individual is **EITHER**:
 - Not an operable candidate for open surgery; **or**
 - Is an operable candidate but at high risk for open surgery (see Policy Guidelines).

The following are considered **investigational**, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

- Transcatheter mitral valve repair in all other situations
- Transcatheter mitral valve implantation/replacement in all other situations
- Transcatheter mitral valve annulus reconstruction

POLICY GUIDELINES

"Prohibitive risk" for open surgery may be determined based on:

- Presence of a Society for Thoracic Surgeons (STS) predicted mortality risk of 12% or greater and/or
- Presence of a logistic EuroSCORE of 20% or greater.

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

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 medical therapy may be determined by guidelines from specialty societies (e.g., American Heart Association/American College of Cardiology Guideline for the Management of Patients with Valvular Heart Disease, European Society of Cardiology/European Association for Cardio-Thoracic Surgery Guidelines for the Management of Valvular Heart Disease, American Heart Association/American College of Cardiology/Heart Failure Society of America Guideline for the Management of Heart Failure).

High risk for open surgery may be defined as the predicted risk of surgical mortality $\geq 8\%$ at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator.

Cross-reference:

- MP 1.135** Transcatheter Aortic Valve Implantation for Aortic Stenosis
- MP 1.139** Transcatheter Pulmonary Valve Implantation

II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

[TOP](#)

Mitral Regurgitation

Epidemiology and Classification

Mitral Regurgitation (MR) is the second most common valvular heart disease, occurring in 7% of people older than age 75 years and accounting for 24% of all patients with valvular heart disease. MR with accompanying valvular incompetence leads to left ventricular (LV) volume overload with secondary ventricular remodeling, myocardial dysfunction, and left heart failure. Clinical signs and symptoms of dyspnea and orthopnea may also be present in patients with

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

valvular dysfunction. MR severity is classified as mild, moderate, or severe disease on the basis of echocardiographic and/or angiographic findings (1+, 2+, and 3-4+ angiographic grade, respectively).

Patients with MR generally fall into two categories -primary (also called degenerative) and secondary (also called functional) MR. Primary MR results from a primary structural abnormality in the valve, which causes it to leak. This leak may result from a floppy leaflet (called prolapse) or a ruptured cord that caused the leaflet to detach partially (called flail). Because the primary cause is a structural abnormality, most cases of primary MR are surgically corrected. Secondary MR results from LV dilatation due to ischemic or dilated cardiomyopathy. This causes the mitral valve (MV) leaflets not to coapt or meet in the center. Because the valves are structurally normal in secondary MR, correcting the dilated LV using medical therapy is the primary treatment strategy used in the U.S.

Standard Management

Surgical Management

In symptomatic patients with primary MR, surgery is the main therapy. In most cases, MV repair is preferred over replacement, as long as the valve is suitable for repair and personnel with appropriate surgical expertise are available. The American College of Cardiology and the American Heart Association have issued joint guidelines on the management of MV. In 2020, the American College of Cardiology and American Heart Association released updated guidelines on the management of valvular heart disease. The guidelines state that TMVR is of benefit to patients with severely symptomatic primary MR who are at high or prohibitive risk for surgery, and to a subset of patients with secondary MR who remain severely symptomatic despite guideline-directed management and therapy for heart failure. Relevant recommendations on interventions for primary and secondary MR are shown in Table 1.

Table 1. Recommendations on Interventions for Primary and Secondary Mitral Regurgitation

Recommendation	COR	LOE
<i>Primary MR</i>		
In symptomatic patients with severe primary MR (Stage D), mitral valve intervention is recommended irrespective of LV systolic function	1(Strong)	B-NR ¹
In asymptomatic patients with severe primary MR and LV systolic dysfunction (LVEF <60%, LVESD >40 mm) (Stage C2), mitral valve surgery is recommended	1(Strong)	B-NR ¹
In patients with severe primary MR for whom surgery is indicated, mitral valve repair is recommended in preference to mitral valve replacement when the anatomic cause of MR is a degenerative disease, if a successful and durable repair is possible	1(Strong)	B-NR ¹
In asymptomatic patients with severe primary MR and normal LV systolic function (LVEF >60% and LVESD >40 mm) (Stage C1), mitral valve repair is reasonable when the likelihood of a successful and	2a (Moderate)	B-NR ¹

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

<p>lasting repair without residual MR is >95% with an expected mortality rate of <1% when it can be performed at a Primary or Comprehensive Valve Center</p>		
<p>In asymptomatic patients with severe primary MR and normal LV systolic function (LVEF >60% and LVESD <40 mm) (Stage C1) but with a progressive increase in LV size or decrease in EF on ≥3 serial imaging studies, mitral valve surgery may be considered irrespective of the probability of a successful and lasting repair</p>	2b (Weak)	C-LD ²
<p>In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, TEER is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year</p>	2a (Moderate)	B-NR ¹
<p>In symptomatic patients with severe primary MR attributable to rheumatic valve disease, mitral valve repair may be considered at a Comprehensive Valve Center by an experienced team when surgical treatment is indicated, if a lasting and successful repair is likely</p>	2b (Weak)	B-NR ¹
<p>In patients with severe primary MR where leaflet pathology is limited to less than one half the posterior leaflet, mitral valve replacement should not be performed unless mitral valve repair has been attempted at a Primary or Comprehensive Valve Center and was unsuccessful</p>	3 (Harm)	B-NR ¹
Secondary MR		
<p>In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD <70 mm, and pulmonary artery systolic pressure <70 mmHg</p>	2a (Moderate)	B-R ³
<p>In patients with severe secondary MR (Stages C and D), mitral valve surgery is reasonable when CABG is undertaken for the treatment of myocardial ischemia</p>	2a (Moderate)	B-NR ¹
<p>In patients with chronic severe secondary MR from atrial annular dilation with preserved LV systolic function (LVEF >50%) who have severe persistent symptoms (NYHA class III or IV) despite therapy for HF and therapy for associated AF or other comorbidities (Stage D), mitral valve surgery may be considered</p>	2b (Weak)	B-NR ¹
<p>In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent severe symptoms (NYHA class III or IV) while on optimal GDMT for HF (Stage D), mitral valve surgery may be considered</p>	2b (Weak)	B-NR ¹
<p>In patients with CAD and chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) (Stage D) who are undergoing mitral valve surgery because of severe symptoms (NYHA class III or IV) that persist despite GDMT for HF, chordal-sparing mitral valve</p>	2b (Weak)	B-R ³

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

replacement may be reasonable to choose over downsized annuloplasty repair		
--	--	--

Source Adapted from Otto et al (2020) ¹Moderate, nonrandomized; ²Limited data; ³Moderate, randomized. AF: atrial fibrillation; CABG: coronary artery bypass graft; CAD: coronary artery disease; COR: class of recommendation; EF: ejection fraction; GDMT: guideline-directed medical therapy; HF: heart failure; LOE: level of evidence; LV: left ventricular; LVEF: left ventricular ejection fraction; LVESD: left ventricular end-systolic diameters; MR: mitral regurgitation; MV: mitral valve; NYHA: New York Heart Association; TEE: transesophageal echocardiogram; TEER: transcatheter edge-to-edge repair

The use of standard open MV repair is limited by the requirement for thoracotomy and cardiopulmonary bypass, which may not be tolerated by elderly or debilitated patients due to their underlying cardiac disease or other conditions. In a single-center evaluation of 5737 patients with severe MR in the U.S., Goel et al (2014) found that 53% of patients did not have MV surgery performed, suggesting an unmet need for such patients. Isolated MV surgery (repair or replacement) for severe chronic secondary MR is not generally recommended because there is no proven mortality reduction and an uncertain durable effect on symptoms.

Recommendations from major societies regarding MV surgery in conjunction with coronary artery bypass graft surgery or surgical aortic valve replacement are weak because the current evidence is inconsistent on whether MV surgery produces a clinical benefit.

Transcatheter MV Repair

Transcatheter approaches have been investigated to address the unmet need for less invasive MV repair, particularly among inoperable patients who face prohibitively high surgical risks due to age or comorbidities. MV repair devices under development address various components of the MV complex and generally are performed on the beating heart without the need for cardiopulmonary bypass. Approaches to MV repair include direct leaflet repair, repair of the mitral annulus via direct annuloplasty, or indirect repair based on the annulus's proximity to the coronary sinus. There are also devices in development to counteract ventricular remodeling, and systems designed for complete MV replacement via catheter.

Direct Leaflet Approximation

Of the TMVR devices under investigation, MitraClip has the largest body of evidence evaluating its use; it has been in use in Europe since 2008. The MitraClip system is deployed percutaneously and approximates the open Alfieri edge-to-edge repair approach to treating MR. The delivery system consists of a catheter, a steerable sleeve, and the MitraClip device, which is a 4-mm wide clip fabricated from a cobalt-chromium alloy and polypropylene fabric. MitraClip is deployed via a transfemoral approach, with transseptal puncture used to access the left side of the heart and the MV. Placement of MitraClip leads to coaptation of the mitral leaflets, thus creating a double-orifice valve.

The PASCAL (PAddles Spacer Clasps ALfieri) Mitral Repair System (Edwards Lifesciences) is also a direct coaptation device and works in a similar manner to the MitraClip system. PASCAL has been in clinical use since 2016 and was approved for use in Europe in 2019. The delivery

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

system consists of a 10-mm central spacer that attaches to the MV leaflets by 2 paddles and clasps.

Other MV Repair Devices

Devices for TMVR that use different approaches are in development. Techniques to repair the mitral annulus include those that target the annulus itself (direct annuloplasty) and those that tighten the mitral annulus via manipulation of the adjacent coronary sinus (indirect annuloplasty). Indirect annuloplasty devices include the Carillon Mitral Contour System (Cardiac Dimension) and the Monarc device (Edwards Lifesciences). The CE-marked Carillon Mitral Contour System is comprised of self-expanding proximal and distal anchors connected with a nitinol bridge, with the proximal end coronary sinus ostium and the distal anchor in the great cardiac vein. The size of the connection is controlled by manual pullback on the catheter (CE-marked). The Carillon system was evaluated in the Carillon Mitral Annuloplasty Device European Union Study and the follow-up Tighten the Annulus Now study, with further studies planned. The Monarc system also involves two self-expanding stents connected by a nitinol bridge, with one end implanted in the coronary sinus via internal jugular vein and the other in the great cardiac vein. Several weeks after implantation, the biologically degradable coating over the nitinol bridge degrades, allowing the bridge to shrink and the system to shorten. It has been evaluated in the Clinical Evaluation of the Edwards Lifesciences Percutaneous Mitral Annuloplasty System for the Treatment of Mitral Regurgitation trial.

Direct annuloplasty devices include the Mitralign Percutaneous Annuloplasty System (Mitralign) and the AccuCinch® System (Guided Delivery Systems), both of which involve transcatheter placement of anchors in the MV; they are cinched or connected to narrow the mitral annulus. Other transcatheter direct annuloplasty devices under investigation include the enCorTC™ device (MiCardia), which involves a percutaneously insertable annuloplasty ring that is adjustable using radiofrequency energy, a variation on its CE-marked enCor_{sq}™ Mitral Valve Repair System, and the Cardioband Annuloplasty System (Valtech Cardio), an implantable annuloplasty band with a transfemoral venous delivery system.

Transcatheter MV Replacement

Permavalve (MicroInterventional Devices), under investigation in the U. S., is a transcatheter MV replacement device that is delivered via the transapical approach. On June 5, 2017, the SAPIEN 3 Transcatheter Heart Valve (Edwards Lifesciences) was approved by the FDA as an MV replacement device. These replacement valves are outside the scope of this evidence review.

Medical Management

The standard treatment for patients with chronic secondary MR is medical management. Patients with chronic secondary MR should receive standard therapy for heart failure with reduced ejection fraction; standard management includes angiotensin converting enzyme inhibitor (or angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor), beta-blocker and mineralocorticoid receptor antagonist, and diuretic therapy as

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

needed to treat volume overload. Resynchronization therapy may provide symptomatic relief, improve LV function, and in some patients, lessen the severity of MR.

Regulatory Status

In October 2013, the MitraClip® Clip Delivery System (Abbott Vascular) was approved by the FDA through the premarket approval process for treatment 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 a prohibitive risk for mitral valve surgery by a heart team.”

In March 2019, the FDA approved a new indication for MitraClip, for "treatment of patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy. Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators."

September 2022, the FDA approved the PASCAL Precision Transcatheter Valve Repair System through premarket approval process for treatment of individuals with significant (a grade greater than or equal to 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.

IV. RATIONALE

[TOP](#)

SUMMARY OF EVIDENCE

For individuals who have symptomatic primary mitral regurgitation (MR) and at prohibitive risk for open surgery who receive transcatheter mitral valve repair (TMVR) using MitraClip or PASCAL, the evidence includes a noninferiority randomized controlled trial (RCT) and single-arm prospective cohort with historical cohort and registry studies. The relevant outcomes are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. The primary evidence includes the pivotal EVEREST II HRR and EVEREST II REALISM studies the Transcatheter Valve Therapy Registry study, and the CLASP IID/IIF study. Studies evaluating MitraClip have demonstrated that MitraClip implantation is feasible with a procedural success rate greater than 90%, 30-day mortality ranging from 2.3% to 6.4% (less than predicted Society of Thoracic Surgeons (STS) mortality risk score for MR repair or replacement; range, 9.5%-13.2%), post implantation MR severity grade of 2+ or less in 82% to 93% of patients, and a clinically meaningful gain in quality of life (5- to 6-point gains in SF-36scores). At 1 year, freedom from death and MR more than 2+ was achieved in 61% of patients but the 1-year mortality or heart failure (HF) hospitalization rates remain considerably high (38%). Conclusions related to the treatment effect on mortality based on historical controls cannot be made because the control groups did not provide unbiased or precise estimates of the natural history of patients eligible to receive MitraClip. Given that primary MR is a mechanical problem and there

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

is no effective medical therapy, a RCT comparing TMVR with medical management is not feasible or ethical. The post marketing data from the U. S. is supportive that MitraClip surgery is being performed with short-term effectiveness and safety in select patient population. The CLASP IID/IIF randomized cohort demonstrated that PASCAL is noninferior to MitraClip in safety and effectiveness for patients with primary MR at prohibitive surgical risk, and the single-arm registry cohort demonstrated that PASCAL is safe and effective in patients with complex mitral valve (MV) anatomy precluding the use of MitraClip. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have heart failure and symptomatic secondary mitral regurgitation (SMR) despite the use of maximally tolerated guideline-directed medical therapy who receive TMVR using MitraClip, the evidence includes a systematic review, two RCTS as well as multiple observational studies. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The trials had discrepant results potentially related to differences in primary outcomes. The larger trial, with patients selected for nonresponse to maximally tolerated therapy, found a significant benefit for MitraClip up to 5 years compared to medical therapy alone, including benefits in overall survival and hospitalization for heart failure. The systematic review confirmed the benefit of MitraClip found in the larger RCT but had important methodological limitations. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have symptomatic primary or SMR and are surgical candidates who receive TMVR using MitraClip, the evidence includes a systematic review, 1 RCT and a retrospective comparative observational study in individuals aged ≥ 75 years. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that MitraClip did not reduce MR as often or as completely as the surgical control, although it could be safely implanted and was associated with fewer adverse events at one year. Long-term follow-up from the RCT showed that significantly more MitraClip patients required surgery for MV dysfunction than conventional surgery patients. For these reasons, this single trial is not definitive in demonstrating improved clinical outcomes with MitraClip compared with surgery. Additional RCTs are needed to corroborate these results. The observational study in individuals aged ≥ 75 years found that although MitraClip was associated with improved 1-year survival and a lower rate of all acute complications compared with surgical repair, it had lower 5-year survival and greater MR recurrence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic primary or secondary MR who receive TMVR using devices other than MitraClip or PASCAL, the evidence includes a randomized study, nonrandomized prospective studies, and noncomparative feasibility studies. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The randomized, sham-controlled trial for the indirect annuloplasty device Carillon offers promising safety data; however, further studies are needed to determine efficacy and long-term outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

For individuals who have a degenerated bio-prosthetic valve, the evidence includes an analysis of the real-world off-label use data captured in the Society of Thoracic Surgeons (STS) /American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry. The registry reported on mortality rates on date of discharge, and 30-day follow-up. 314 cases of individuals who had undergone aortic valve-in-valve procedures and 311 cases who had undergone mitral valve-in-valve procedures, of which only 70 individuals utilized the SAPIEN 3 device. Registry data showed that more than 93 percent of individuals (n=40) who underwent and had 30-day follow-up information in the mitral valve-in-valve procedures with SAPIEN 3 experienced clinically meaningful improvement in their heart failure symptoms 30-days post procedure, demonstrated by their New York Heart Association (NYHA) Classifications. The individuals in the SAPIEN 3 cohort also acknowledged an increase in quality of life according to the Kansas City Cardiomyopathy Questionnaire (KCCQ) (scale 0-100), more than doubling from the date of discharge to the 30-day follow-up. In either of the valve-in-valve procedures, the recipients observed mortality rates were substantially lower than the expected mortality rate for revision surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS

N/A

[TOP](#)

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

[TOP](#)

VII. DISCLAIMER

Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

[TOP](#)

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

VIII. CODING INFORMATION

[TOP](#)

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure Codes							
0484T	0544T						

Covered when medically necessary:

Procedure Codes							
33418	33419	0345T	0483T				

ICD-10-CM Diagnosis Codes	Description
I05.1	Rheumatic mitral insufficiency
I05.2	Rheumatic mitral stenosis with insufficiency
I05.8	Other rheumatic mitral valve diseases
I05.9	Rheumatic mitral valve disease, unspecified
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.1	Rheumatic disorders of both mitral and tricuspid valves
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral (valve) prolapse
I34.2	Nonrheumatic mitral (valve) stenosis
I34.9	Nonrheumatic mitral valve disorder, unspecified

IX. REFERENCES

[TOP](#)

1. Chiam PT, Ruiz CE. Percutaneous transcatheter mitral valve repair: a classification of the technology. *JACC Cardiovasc Interv.* Jan 2011; 4(1): 1-13. PMID 21251623
2. Fedak PW, McCarthy PM, Bonow RO. Evolving concepts and technologies in mitral valve repair. *Circulation.* Feb 19 2008; 117(7): 963-74. PMID 18285577
3. Carabello BA. The current therapy for mitral regurgitation. *J Am Coll Cardiol.* Jul 29 2008; 52(5): 319-26. PMID 18652937
4. Bonow RO, Carabello BA, Chatterjee K, et al. 2008 focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to revise the 1998 guidelines for the

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

- management of patients with valvular heart disease). Endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. Sep 23 2008; 52(13): e1-142. PMID 18848134*
5. *Otto CM, Nishimura RA, Bonow RO, et al. 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. Feb 02 2021; 143(5): e72-e227. PMID 33332150*
 6. *Goel SS, Bajaj N, Aggarwal B, et al. Prevalence and outcomes of unoperated patients with severe symptomatic mitral regurgitation and heart failure: comprehensive analysis to determine the potential role of MitraClip for this unmet need. J Am Coll Cardiol. Jan 21 2014; 63(2): 185-6. PMID 24036029*
 7. *Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. Jul 11 2017; 70(2): 252-289. PMID 28315732*
 8. *Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012). Eur Heart J. Oct 2012; 33(19): 2451-96. PMID 22922415*
 9. *Diodato MD, Moon MR, Pasque MK, et al. Repair of ischemic mitral regurgitation does not increase mortality or improve long-term survival in patients undergoing coronary artery revascularization: a propensity analysis. Ann Thorac Surg. Sep 2004; 78(3): 794-9; discussion 794-9. PMID 15336993*
 10. *Wong DR, Agnihotri AK, Hung JW, et al. Long-term survival after surgical revascularization for moderate ischemic mitral regurgitation. Ann Thorac Surg. Aug 2005; 80(2): 570-7. PMID 16039207*
 11. *Mihaljevic T, Lam BK, Rajeswaran J, et al. Impact of mitral valve annuloplasty combined with revascularization in patients with functional ischemic mitral regurgitation. J Am Coll Cardiol. Jun 05 2007; 49(22): 2191-201. PMID 17543639*
 12. *Smith PK, Puskas JD, Ascheim DD, et al. Surgical treatment of moderate ischemic mitral regurgitation. N Engl J Med. Dec 04 2014; 371(23): 2178-88. PMID 25405390*
 13. *Young A, Feldman T. Percutaneous mitral valve repair. Curr Cardiol Rep. Jan 2014; 16(1): 443. PMID 24281977*
 14. *Minha S, Torguson R, Waksman R. Overview of the 2013 Food and Drug Administration Circulatory System Devices Panel meeting on the MitraClip Delivery System. Circulation. Aug 20 2013; 128(8): 864-8. PMID 23960257*
 15. *Noack T, Kiefer P, Besler C, et al. Transcatheter mitral valve repair: review of current techniques. Indian J Thorac Cardiovasc Surg. Jan 2020; 36(Suppl 1): 53-63. PMID 33061185*
 16. *Corpataux N, Winkel MG, Kassab M, et al. The PASCAL Device-Early Experience with a Leaflet Approximation Device: What Are the Benefits/Limitations Compared with the MitraClip?. Curr Cardiol Rep. Jun 27 2020; 22(8): 74. PMID 32594261*
 17. *Siminiak T, Wu JC, Haude M, et al. Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial. Eur J Heart Fail. Aug 2012; 14(8): 931-8. PMID 22613584*

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

18. Harnek J, Webb JG, Kuck KH, et al. Transcatheter implantation of the MONARC coronary sinus device for mitral regurgitation: 1-year results from the EVOLUTION phase I study (Clinical Evaluation of the Edwards Lifesciences Percutaneous Mitral Annuloplasty System for the Treatment of Mitral Regurgitation). *JACC Cardiovasc Interv.* Jan 2011; 4(1): 115-22. PMID 21251638
19. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Mitral Valve Repair Device. 2013
20. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous mitral valve repair. *TEC Assessments 2014; Volume 29: Tab 4*
21. Lim DS, Smith RL, Gillam LD, et al. Randomized Comparison of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation in Prohibitive Surgical Risk Patients. *JACC Cardiovasc Interv.* Dec 26 2022; 15(24): 2523-2536. PMID 36121247
22. ClinicalTrials.gov. Edwards PASCAL CLASP IID/IIF Pivotal Clinical Trial (CLASP IID/IIF) (NCT03706833). 2023
23. Reichenspurner H, Schillinger W, Baldus S, et al. Clinical outcomes through 12 months in patients with degenerative mitral regurgitation treated with the MitraClip(R) device in the ACCESS-EUrope Phase I trial. *Eur J Cardiothorac Surg.* Oct 2013; 44(4): e280-8. PMID 23864216
24. Lim S, Kar S, Fail P, et al. The EVEREST II high surgical risk cohort: effectiveness of transcatheter reduction of significant mitral regurgitation in high surgical risk patients. *J Am Coll Cardiol.* 2013;61(10 Suppl):E1958
25. Lim DS, Reynolds MR, Feldman T, et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation after transcatheter mitral valve repair. *J Am Coll Cardiol.* Jul 15 2014; 64(2): 182-92. PMID 24184254
26. Ware J, Kosinski M, Bjorner JB, et al. User's Manual for the SF-36v2 Health Survey (2nd Ed). Lincoln, RI: QualityMetric; 2007
27. Sorajja P, Mack M, Vemulapalli S, et al. Initial Experience With Commercial Transcatheter Mitral Valve Repair in the United States. *J Am Coll Cardiol.* Mar 15 2016; 67(10): 1129-1140. PMID 26965532
28. Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol.* Nov 07 2017; 70(19): 2315-2327. PMID 29096801
29. Glower DD, Kar S, Trento A, et al. Percutaneous mitral valve repair for mitral regurgitation in high-risk patients: results of the EVEREST II study. *J Am Coll Cardiol.* Jul 15 2014; 64(2): 172-81. PMID 25011722
30. Gerçek M, 12rder F, Rudolph TK, et al. PASCAL mitral valve repair system versus MitraClip: comparison of transcatheter edge-to-edge strategies in complex primary mitral regurgitation. *Clin Res Cardiol.* Dec 2021; 110(12): 1890-1899. PMID 33837469
31. Hausleiter J, Lim DS, Gillam LD, et al. Transcatheter Edge-to-Edge Repair in Patients With Anatomically Complex Degenerative Mitral Regurgitation. *J Am Coll Cardiol.* Feb 07 2023; 81(5): 431-442. PMID 36725171
32. Feldman T, Kar S, Rinaldi M, et al. Percutaneous mitral repair with the MitraClip system: safety and midterm durability in the initial EVEREST (Endovascular Valve Edge-to-Edge REpair Study) cohort. *J Am Coll Cardiol.* Aug 18 2009; 54(8): 686-94. PMID 19679246

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

33. Chan PH, She HL, Alegria-Barrero E, et al. Real-world experience of MitraClip for treatment of severe mitral regurgitation. *Circ J*. 2012; 76(10): 2488-93. PMID 22785461
34. Whitlow PL, Feldman T, Pedersen WR, et al. 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*. Jan 10 2012; 59(2): 130-9. PMID 22222076
35. 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*. Nov 2013; 2(6): 683-92. PMID 24349969
36. Bail DH, Doebler K. The MitraClip System: a systematic review of indications, procedural requirements, and guidelines. *Thorac Cardiovasc Surg*. Feb 2014; 62(1): 18-25. PMID 24297637
37. Estevez-Loureiro R, Franzen O, Winter R, et al. Echocardiographic and clinical outcomes of central versus noncentral percutaneous edge-to-edge repair of degenerative mitral regurgitation. *J Am Coll Cardiol*. Dec 24 2013; 62(25): 2370-2377. PMID 24013059
38. Grasso C, Ohno Y, Attizzani GF, et al. Percutaneous mitral valve repair with the MitraClip system for severe mitral regurgitation in patients with surgical mitral valve repair failure. *J Am Coll Cardiol*. Mar 04 2014; 63(8): 836-8. PMID 24161329
39. Munkholm-Larsen S, Wan B, Tian DH, et al. A systematic review on the safety and efficacy of percutaneous edge-to-edge mitral valve repair with the MitraClip system for high surgical risk candidates. *Heart*. Mar 2014; 100(6): 473-8. PMID 23813844
40. Swaans MJ, Bakker AL, Alipour A, et al. Survival of transcatheter mitral valve repair compared with surgical and conservative treatment in high-surgical-risk patients. *JACC Cardiovasc Interv*. Aug 2014; 7(8): 875-81. PMID 25147032
41. 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*. Oct 01 2014; 84(4): 581-90. PMID 24905665
42. Vakil K, Roukoz H, Sarraf M, et al. Safety and efficacy of the MitraClip(R) system for severe mitral regurgitation: a systematic review. *Catheter Cardiovasc Interv*. Jul 01 2014; 84(1): 129-36. PMID 24323764
43. Bail DH. (Meta)-analysis of safety and efficacy following edge-to-edge mitral valve repair using the MitraClip system. *J Interv Cardiol*. Feb 2015; 28(1): 69-75. PMID 25689550
44. Velazquez EJ, Samad Z, Al-Khalidi HR, et al. The MitraClip and survival in patients with mitral regurgitation at high risk for surgery: A propensity-matched comparison. *Am Heart J*. Nov 2015; 170(5): 1050-1059.e3. PMID 26542516
45. Hayashida K, Yasuda S, Matsumoto T, et al. AVJ-514 Trial - Baseline Characteristics and 30-Day Outcomes Following MitraClip (R) Treatment in a Japanese Cohort. *Circ J*. Jul 25 2017; 81(8): 1116-1122. PMID 28321004
46. Srinivasan A, Brown J, Ahmed H, et al. PASCAL repair system for patients with mitral regurgitation: A systematic review. *Int J Cardiol*. Apr 01 2023; 376: 108-114. PMID 36681242
47. Kumar A, Al-Khafaji J, Shariff M, et al. Percutaneous mitral valve repair for secondary mitral valve regurgitation: A systematic review and meta-analysis. *Eur J Intern Med*. Aug 2020; 78: 107-112. PMID 32094019

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

48. Szerlip M, Spargias KS, Makkar R, et al. 2-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study. *JACC Cardiovasc Interv.* Jul 26 2021; 14(14): 1538-1548. PMID 34020928
49. Obadia JF, Messika-Zeitoun D, Leurent G, et al. Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation. *N Engl J Med.* Dec 13 2018; 379(24): 2297-2306. PMID 30145927
50. Atianzar K, Zhang M, Newhart Z, et al. Why Did COAPT Win While MITRA-FR Failed? Defining the Appropriate Patient Population for MitraClip. *Interv Cardiol.* Feb 2019; 14(1): 45-47. PMID 30858892
51. Iung B, Armoiry X, Vahanian A, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation: outcomes at 2 years. *Eur J Heart Fail.* Dec 2019; 21(12): 1619-1627. PMID 31476260
52. Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter Mitral-Valve Repair in Patients with Heart Failure. *N Engl J Med.* Dec 13 2018; 379(24): 2307-2318. PMID 30280640
53. Stone GW, Abraham WT, Lindenfeld J, et al. Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation. *N Engl J Med.* Mar 05 2023. PMID 36876756
54. Mack MJ, Lindenfeld J, Abraham WT, et al. 3-Year Outcomes of Transcatheter Mitral Valve Repair in Patients With Heart Failure. *J Am Coll Cardiol.* Mar 02 2021; 77(8): 1029-1040. PMID 33632476
55. Nishimura RA, Bonow RO. Percutaneous Repair of Secondary Mitral Regurgitation - A Tale of Two Trials. *N Engl J Med.* Dec 13 2018; 379(24): 2374-2376. PMID 30575469
56. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Card Fail.* Aug 2017; 23(8): 628-651. PMID 28461259
57. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* Sep 21 2017; 38(36): 2739-2791. PMID 28886619
58. Orban M, Rottbauer W, Williams M, et al. Transcatheter edge-to-edge repair for secondary mitral regurgitation with third-generation devices in heart failure patients - results from the Global EXPAND Post-Market study. *Eur J Heart Fail.* Mar 2023; 25(3): 411-421. PMID 36597850
59. Takagi H, Ando T, Umemoto T. A review of comparative studies of MitraClip versus surgical repair for mitral regurgitation. *Int J Cardiol.* Feb 01 2017; 228: 289-294. PMID 27865200
60. Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. *N Engl J Med.* Apr 14 2011; 364(15): 1395-406. PMID 21463154
61. Mauri L, Garg P, Massaro JM, et al. The EVEREST II Trial: design and rationale for a randomized study of the Evalve mitralclip system compared with mitral valve surgery for mitral regurgitation. *Am Heart J.* Jul 2010; 160(1): 23-9. PMID 20598968
62. Mauri L, Foster E, Glower DD, et al. 4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation. *J Am Coll Cardiol.* Jul 23 2013; 62(4): 317-28. PMID 23665364

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

63. Feldman T, Kar S, Elmariah S, et al. Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation: 5-Year Results of EVEREST II. *J Am Coll Cardiol.* Dec 29 2015; 66(25): 2844-2854. PMID 26718672
64. McCarthy PM, Whisenant B, Asgar AW, et al. Percutaneous MitraClip Device or Surgical Mitral Valve Repair in Patients With Primary Mitral Regurgitation Who Are Candidates for Surgery: Design and Rationale of the REPAIR MR Trial. *J Am Heart Assoc.* Feb 21 2023; 12(4): e027504. PMID 36752231
65. Buzzatti N, Van Hemelrijck M, Denti P, et al. Transcatheter or surgical repair for degenerative mitral regurgitation in elderly patients: A propensity-weighted analysis. *J Thorac Cardiovasc Surg.* Jul 2019; 158(1): 86-94.e1. PMID 30797588
66. Witte KK, Lipiecki J, Siminiak T, et al. The REDUCE FMR Trial: A Randomized Sham-Controlled Study of Percutaneous Mitral Annuloplasty in Functional Mitral Regurgitation. *JACC Heart Fail.* Nov 2019; 7(11): 945-955. PMID 31521683
67. Khan MS, Siddiqi TJ, Butler J, et al. Functional outcomes with Carillon device over 1 year in patients with functional mitral regurgitation of Grades 2+ to 4+: results from the REDUCE-FMR trial. *ESC Heart Fail.* Apr 2021; 8(2): 872-878. PMID 33619896
68. Schofer J, Siminiak T, Haude M, et al. Percutaneous mitral annuloplasty for functional mitral regurgitation: results of the CARILLON Mitral Annuloplasty Device European Union Study. *Circulation.* Jul 28 2009; 120(4): 326-33. PMID 19597051
69. 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.* May 05 2020; 75(17): 2236-2270. PMID 32068084
70. O'Gara PT, Calhoun JH, Moon MR, et al. Transcatheter therapies for mitral regurgitation: a professional society overview from the American College of Cardiology, The American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions Foundation, and The Society of Thoracic Surgeons. *J Thorac Cardiovasc Surg.* Mar 2014; 147(3): 837-49. PMID 24529172
71. National Institute for Health and Care Excellence (NICE). Heart valve disease presenting in adults: investigation and management [NG208]. 2021
72. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Transcatheter MITRAL Valve Repair (TMVR) (20.33). 2021
73. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Prosthesis, Mitral Valve, Percutaneously Delivered. 2021.
74. 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;5(11):1245-1252. doi:10.1001/jamacardio.2020.2974
75. Castillo A and Zamorano P. Management and Prognosis of Surgical Aortic and Mitral Prosthetic Valve Regurgitation. In: *UpToDate Online Journal* [serial online]. Waltham, MA: UpToDate; updated October 1, 2019. Literature review current through May 2021.
76. Independence Blue Cross Policy Number 11.02.25g, Transcatheter Cardiac Valve Procedures. January 1, 2020.
77. Food and Drug Administration. PASCAL Precision Transcatheter Valve Repair System, 2022.

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER MITRAL VALVE PROCEDURES
POLICY NUMBER	MP 1.153

78. Alperi A, Avanzas P, Leon V, et al. Current status of transcatheter mitral valve replacement: systematic review and meta-analysis. *Frontiers in Cardiovascular Medicine*. 2023;10.
79. Eleid MF, Collins JD, Mahoney P, et al. Emerging Approaches to Management of Left Ventricular Outflow Obstruction Risk in Transcatheter Mitral Valve Replacement. *JACC Cardiovasc Interv*. 2023;16(8):885-895. PMID 37100552
80. Ludwig S, Conradi L, Cohen DJ, et al. Transcatheter mitral valve Replacement versus Medical therapy for secondary mitral regurgitation: A Propensity Score–Matched Comparison. *Circulation Cardiovascular Interventions*. 2023;16(6).
81. Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.02.30, Transcatheter Mitral Valve Repair. June 2023

X. POLICY HISTORY

[Top](#)

MP 1.153	06/09/2020 Consensus Review. Policy Statement unchanged. Cross references updated. Product Variation updated. References reviewed and updated. FEP reviewed. Code 0483T added.
	06/18/2021 Minor Review. Added Transcatheter mitral valve replacement of a degenerated bio-prosthetic valve (valve-in-valve) with a device approved by U.S. Food and Drug Administration may be considered medically necessary when criteria are met. Changed name of the policy to Transcatheter Mitral Valve Procedures. Updated policy guidelines, cross references, background, rationale, coding and references. Took 0484T from E/I policy and placed in this policy.
	10/01/2022 Administrative Update. I348 deleted from policy as a deleted code.
	12/08/2022 Consensus Review. Policy statement unchanged. Regulatory status and references reviewed and updated. FEP statement updated. Coding reviewed.
	05/18/2023 Consensus Review. Policy statement unchanged. References reviewed and updated. Background, regulatory statement and rationale updated. Table 1 updated to 2020 guidelines for MR. No coding changes.
	06/07/2024 Consensus Review. No change to policy statement. References reviewed and updated. No coding changes.

[Top](#)

Health care benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company[®], Capital Advantage Assurance Company[®] and Keystone Health Plan[®] Central. Independent licensees of the Blue Cross BlueShield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.