LOUISIANA BLUE

Transcatheter Mitral Valve Replacement or Edge to Edge Repair

Policy # 00494
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Transcatheter Aortic Valve Implantation for Aortic Stenosis is addressed separately in medical policy 00406.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider mitral transcatheter edge-to-edge repair (M-TEER) for treatment of primary mitral regurgitation to be **eligible for coverage**** when **ALL** of the following criteria are met:

- A device is approved by the U.S. Food and Drug Administration (FDA) for the requested indication (e.g., MitraClip NT and NTR/XTR Clip Delivery Systems, PASCAL Precision Transcatheter Valve Repair System); **AND**
- For treatment of symptomatic primary mitral regurgitation (MR) grade 3+ (moderate-to-severe) or 4+ (severe) confirmed by echocardiography; **AND**
- For individuals who have prohibitive risk for open surgery as determined by a multidisciplinary heart team.

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

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

Based on review of available data, the Company may consider mitral transcatheter edge-to-edge repair (M-TEER) for treatment of secondary (functional) mitral regurgitation to be **eligible for coverage**** when **ALL** of the following criteria are met:

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- A device is approved by the U.S. FDA for the requested indication (e.g., MitraClip NT and NTR/XTR Clip Delivery System); **AND**
- For treatment of symptomatic secondary (functional) mitral regurgitation (MR) grade 3+ (moderate-to-severe) or 4+ (severe) confirmed by echocardiography; **AND**
- Documented symptomatic heart failure with New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory); **AND**
- Left ventricular ejection fraction (LVEF) is between 20-50%; **AND**
- Left ventricular end systolic dimension (LVESD) is less than or equal to 70 mm; **AND**
- Heart failure symptoms persist 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.

Based on review of available data, the Company may consider valve-in-valve transcatheter mitral valve replacement (ViV-TMVR) to be **eligible for coverage**** when **ALL** of the following criteria are met:

- A device is approved by the U.S. FDA for the requested indication (e.g., Edwards SAPIEN 3 Transcatheter Heart Valve); **AND**
- Treatment for failure (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve; **AND**
- Documented symptomatic heart failure with NYHA functional class II, III, or IV symptoms despite the use of stable maximal doses of guideline-directed medical therapy; **AND**
- One of the following surgical risks:
    - Individual is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); **OR**
    - Individual is an operable candidate but is considered at intermediate to prohibitive surgical risk for open surgery, as documented by at least 2 cardiac specialists (including a cardiac surgeon); **OR**
    - Individual is considered at an intermediate to prohibitive surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); **OR**
    - Individual is considered at an intermediate to prohibitive surgical risk for open surgery (e.g., repeat sternotomy) due to a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon).

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

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

The FDA definition of high risk for open surgery is:

- *Society of Thoracic Surgeons (STS) predicted operative risk score of 8% or higher; or*

- *Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.*

The FDA definition of intermediate risk for open surgery is:

- *Society of Thoracic Surgeons (STS) predicted operative risk score of 4% or higher judged by a heart team.*

When Services Are Considered Not Medically Necessary

The use of mitral transcatheter edge-to-edge repair (M-TEER) for treatment of primary or secondary (functional) mitral regurgitation when patient selection criteria are not met is considered **not medically necessary.****

The use of valve-in-valve transcatheter mitral valve replacement (ViV-TMVR) when patient selection criteria are not met is considered **not medically necessary.****

When Services are Considered Investigational

Based on review of available data, the Company considers native transcatheter mitral valve replacement (TMVR) (e.g., Tendyne™‡ and SAPIEN M3™‡ systems) for all indications, including treatment of severe mitral annular calcification (ViMAC), to be **investigational.***

Based on review of available data, the Company considers valve-in-ring transcatheter mitral valve replacement (ViR-TMVR, e.g., SAPIEN 3) for all indications to be **investigational.***

Policy Guidelines

Moderate to severe or severe mitral regurgitation (MR) may be determined by:

- Grade 3+ (moderate-to-severe) 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 [refer to supplemental materials for guideline citations]).

A multidisciplinary heart team typically includes interventional cardiologists experienced in the procedure, cardiac surgeons, and advanced cardiac imaging specialist.

Background/Overview

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 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+ to 4+ angiographic grade, respectively).

Patients with MR generally fall into 2 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 surgical management of MR (See Supplemental Information).

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.

Mitral Transcatheter Edge-to-Edge 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
Devices currently approved by the FDA for mitral transcatheter edge-to-edge repair (M-TEER) undergo direct mitral leaflet repair. Of the M-TEER 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 coapting 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 system consists of a 10-mm central spacer that attaches to the MV leaflets by 2 paddles and clasps.

Other Mitral Valve Repair Devices
Devices for transcatheter mitral valve repair 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 a manual pull back on the catheter. 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 2 self-expanding stents connected by a nitinol bridge, with one end implanted in the coronary sinus via the 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

transcutaneous 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 Mitral Valve Replacement
Native transcatheter mitral valve replacement (TMVR) delivers a bioprosthetic valve into the native mitral annulus, without cardiopulmonary bypass, in patients who are unsuitable for both surgery and M-TEER. Because the native annulus is a noncircular, dynamic structure that lacks the rigid frame a failed surgical bioprosthesis provides, these systems rely on dedicated anchoring mechanisms., Two devices have received U.S. Food and Drug Administration approval: the Tendyne system (Abbot) is approved for mitral valve dysfunction due to severe mitral annular calcification, and the SAPIEN M3 system (Edwards Life Sciences) for moderate-to-severe or severe mitral regurgitation, each in patients unsuitable for surgery or M-TEER.

Valve-in-Valve Transcatheter Mitral Valve Replacement
Mitral valve-in-valve replacement is a minimally invasive procedure designed to treat patients with failing surgical bioprosthetic mitral valves who are at high risk for complications with repeat open-heart surgery. The Edwards SAPIEN 3 Transcatheter Heart Valve received FDA approval in June 2017 (PMA #P140031) for patients with a failing surgical bioprosthetic mitral valve who are at high or prohibitive risk for repeat surgery. The procedure involves deploying the replacement valve within the failing bioprosthetic valve using a catheter-based transapical or transseptal approach. Once in position, the replacement valve is expanded, pushing the leaflets of the failing bioprosthetic valve aside and taking over the valve function.

Transcatheter Mitral Valve-in-Ring Replacement
Transcatheter mitral valve-in-ring replacement (TMViR) is performed in patients with a failed prior surgical mitral valve repair that included placement of an annuloplasty ring. The procedure involves implantation of a transcatheter heart valve within the existing annuloplasty ring. TMViR differs from transcatheter mitral valve-in-valve replacement (TMViVR), which is performed within a failed surgical bioprosthetic valve, and from native transcatheter mitral valve replacement (TMVR), which is performed in the absence of a prior prosthetic valve or annuloplasty ring.

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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."

The MitraClip Clip Delivery System has since been phased out and is no longer in commercial distribution. The MitraClip NT Clip Delivery System and MitraClip NTR/XTR Clip Delivery System are design iterations of the MitraClip Clip Delivery System approved under the original PMA.

In March 2019, the FDA approved a new indication and noted: "The MitraClip NT Clip Delivery System and MitraClip NTR/XTR Clip Delivery System, when used with maximally tolerated guideline-directed medical therapy (GDMT), are indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR ≥ Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease." Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators.

The MitraClip NT Clip Delivery System and MitraClip NTR/XTR Clip Delivery System are contraindicated in patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

In September 2022, the FDA approved the PASCAL Precision Transcatheter Valve Repair System 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 prohibitive risk for mitral valve surgery by a heart team."

In June 2017, the Edwards SAPIEN 3 Transcatheter Heart Valve received FDA approval through the premarket approval process for the treatment of patients with a "failing surgical bioprosthetic mitral valve who have been determined to be at high or greater risk for open-heart surgery by a heart team."

In May 2021, FDA approved an expanded indication for the Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System to treat patients with symptomatic heart disease due to a failing native mitral valve with a prior annuloplasty ring (valve-in-ring [ViR]) who are considered high or greater surgical risk for open surgery by a multidisciplinary heart team. The approval was based on PMA supplement P140031/S125.

In March 2024, the FDA expanded the indication for the Edwards SAPIEN 3 Systems to include, "patients with a failing surgical bioprosthetic mitral valve who are at intermediate risk for open surgical therapy."

In May 2024, the FDA granted 4C Medical Technologies' AltaValve™‡ System dual Breakthrough Device Designation for the treatment of moderate-to-severe or severe MR, including cases with significant mitral annular calcification (MAC).

In May 2025, the FDA approved Abbott Medical's Tendyne Transcatheter Mitral Valve System™‡ through the premarket approval process for "treatment of symptomatic severe mitral valve dysfunction (moderate-to-severe or severe MR, severe MS, or moderate MR with moderate or greater MS) associated with severe mitral annular calcification (MAC) in patients who are deemed unsuitable for mitral valve surgery or transcatheter edge-to-edge repair by a multidisciplinary heart team."

In December 2025, the FDA approved the Edwards SAPIEN M3 Transcatheter Mitral Valve Replacement System through the premarket approval process for "treatment of symptomatic moderate-to-severe or severe MR in patients who are deemed unsuitable for surgery or transcatheter edge-to-edge repair (M-TEER) therapy by a multidisciplinary heart team." The SAPIEN M3 system is also indicated for "treatment of symptomatic mitral valve dysfunction (moderate-to-severe or severe MR, severe MS, or moderate MR with moderate MS) associated with MAC in patients who are deemed unsuitable for surgery or M-TEER therapy by a multidisciplinary heart team."

FDA product code for MitraClip and PASCAL: NKM.
FDA product code for Edwards SAPIEN 3: NPV.
FDA product code for Tendyne and Edwards SAPIEN 3 M3: NPU.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Mitral transcatheter edge-to-edge repair (M-TEER) and replacement are alternatives to surgical therapy for mitral regurgitation (MR). MR is a common valvular heart disease that can result from a primary structural abnormality of the mitral valve (MV) complex or a secondary dilatation of an

anatomically normal MV due to a dilated left ventricle caused by ischemic or dilated cardiomyopathy. Surgical therapy may be underutilized, particularly in patients with multiple comorbidities, suggesting that there is an unmet need for less invasive procedures for MV repair. Two devices, MitraClip™‡ and PASCAL™‡, have approval from the U.S. Food and Drug Administration for the treatment of severe symptomatic MR due to a primary abnormality of the MV (primary MR) in patients considered at prohibitive risk for surgery. MitraClip is also approved for patients with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy. Two devices for native transcatheter mitral valve replacement (TMVR) received approval in patients unsuitable for surgery or transcatheter edge-to-edge repair: the Tendyne™‡ system, for mitral valve dysfunction associated with severe mitral annular calcification, and the SAPIEN M3™‡ system, for symptomatic moderate-to-severe or severe mitral regurgitation. The Edwards SAPIEN 3 transcatheter heart valve has been approved by the U.S. Food and Drug Administration for valve-in-valve transcatheter mitral valve replacement (ViV-TMVR) in patients with a failing surgical bioprosthetic mitral valve who are at high or greater risk for repeat surgery.

Summary of Evidence

For individuals who have symptomatic primary mitral regurgitation (MR) and are at prohibitive risk for open surgery who receive mitral transcatheter edge-to-edge repair (M-TEER) using MitraClip or PASCAL, the evidence includes a noninferiority randomized controlled trial (RCT) and single-arm prospective cohort with historical cohort and registry studies. 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% to 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-36 scores). 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 is no effective medical therapy, an RCT comparing M-TEER with medical management is not feasible or ethical. The postmarketing data from the U.S. is supportive that MitraClip surgery is being performed with short-term effectiveness and safety in a 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 an improvement in the net health outcome.

For individuals who have HF and symptomatic secondary mitral regurgitation (SMR) despite the use of maximally tolerated guideline-directed medical therapy who receive M-TEER using

MitraClip, the evidence includes a systematic review, 2 RCTs, and 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. Improvements in MR severity, quality of life measures, and functional capacity persisted to 36 months in patients who received M-TEER. 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 an improvement in the net health outcome.

For individuals who have symptomatic primary or secondary MR and are surgical candidates who receive M-TEER using MitraClip, the evidence for the use of MitraClip in patients considered candidates for open MV repair surgery includes 2 RCTs (EVEREST II and MATTERHORN), a retrospective comparative observational study in individuals aged 75 years or more, and a systematic review. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. One RCT found that MitraClip was non-inferior to surgical repair for composite outcomes assessing death from any cause, hospitalization for heart failure, mitral-valve reintervention, implantation of a left ventricular assist device, or stroke within 1 year of the procedure with significantly fewer major adverse events. However, the rate of MR recurrence at 1 year was significantly greater in the MitraClip group. The trial was limited by the short duration of follow-up, high degree of missing data for some outcome measures, and potential confounding from differences in baseline characteristics and a lower degree of triple heart failure medication therapy as well as renin–angiotensin–aldosterone system inhibitors in the surgical group. Another 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 1 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, evidence from these two trials 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 or more 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 that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic primary or secondary MR and are surgical candidates who receive M-TEER using MitraClip, the evidence includes a systematic review, 1 RCT, and a retrospective comparative observational study in individuals aged 75 years or more. 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 1 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 or more 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 that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic primary or secondary MR who receive M-TEER 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 that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic moderate-to-severe or severe MR without severe MAC, or symptomatic severe MAC-associated mitral valve dysfunction, who are deemed unsuitable for surgery or M-TEER and receive native transcatheter mitral valve replacement (TMVR) with an FDA-approved device, the evidence includes 2 single-arm pivotal studies, a retrospective single-center propensity-matched comparison with surgical mitral valve replacement (SMVR), and several registry studies. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The primary evidence can be separated by device. For the transapical Tendyne system, evidence includes the severe MAC cohort of SUMMIT, a retrospective matched comparison with SMVR, and the TENDER and Tendyne Expanded registries. SUMMIT-MAC met its prespecified performance goal for freedom from all-cause mortality and heart failure hospitalization at 12 months, and registries demonstrated high technical success and durable MR elimination through 1 to 2 years, although mortality and heart failure rehospitalization remained substantial. For the transseptal SAPIEN M3 system, evidence includes the ENCIRCLE pivotal trial in moderate-to-severe or severe MR, the ENCIRCLE MAC registry described in the FDA Summary of Safety and Effectiveness Data, and a multicenter registry evidence using mixed dedicated TMVR devices. ENCIRCLE met its prespecified 1-year performance goal for all-cause mortality or heart failure hospitalization, and the MAC registry reported MR reduction and improved NYHA functional class, 6-minute walk distance, and KCCQ at 1 year. In the mixed-device registry, moderate-to-severe MAC was associated with higher periprocedural bleeding and renal failure but similar 2-year survival compared with none or mild MAC; however, this registry pooled several non-FDA-approved devices and did not report outcomes by device. Conclusions regarding the treatment effect cannot be drawn because pivotal evidence was benchmarked against historical performance goals rather than concurrent comparators, substantial mortality and rehospitalization were reported at 1 and 2 year follow-up, the single comparative study was retrospective and had residual confounding, study cohorts were heterogeneous in devices, access routes, and indications, and no published RCT or prospective study has compared native TMVR with surgery, M-TEER, or guideline-directed medical therapy. Randomized comparative data remain pending; SUMMIT includes a randomized Tendyne cohort comparing TMVR with M-TEER, and APOLLO is evaluating another native TMVR system, Intrepid, against surgery. Although the 2025 AATS expert consensus document assigned a Class IIa recommendation (Level B-NR) for TMVR (reasonable in selected high-risk patients with severe

MAC), the 2025 ESC/EACTS valvular heart disease guideline assigned this indication a weaker Class IIb, Level C recommendation (noted that treatment options are high-risk procedures and mortality remains high even after successful treatment). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have valve dysfunction and mitral stenosis or regurgitation after prior bioprosthetic mitral valve replacement, who are at intermediate to prohibitive risk for redo surgical mitral valve replacement (rSMVR), and who receive a valve-in-valve-transcatheter mitral valve replacement (ViV-TMVR) using an FDA-approved device, the evidence includes 2 meta-analyses, 8 comparative retrospective cohort studies, and 9 observational studies. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The meta-analyses had mixed early-term findings, with one observing a benefit for in-hospital mortality favoring ViV-TMVR over rSMVR, but at 30 days, 1-year, and 2-year follow-up, no difference between groups in OS was observed in either review. Both analyses found that complications of stroke, renal dysfunction, vascular complications, pacemaker implantation, and bleeding were more common in the rSMVR group. The comparative studies generally found that mortality was equivalent or favored ViV-TMVR through 1-year follow-up; however, several studies that reported longer-term outcomes observed that the trend in mortality was reversed with numerically higher rates in the ViV-TMVR group. ViV-TMVR was associated with a shorter hospital or ICU stay than rSMVR. Several adverse events (acute kidney injury, cardiac arrest, cardiogenic shock, major bleeding, pacemaker implantation, pneumonia, sepsis, stroke, and vascular complications) were more commonly reported in the rSMVR group compared to ViV-TMVR. These results were supported by observational data, which provided data on mortality, functional outcomes, and complications through up to 7 years post-implantation. The evidence base is limited primarily by the lack of experimental studies, but assigning patients who are at high or prohibitive risk for open surgery to rSMVR is ethically prohibitive so retrospective comparisons will likely continue to represent the best available evidence for this intervention. The evidence for the use of ViV-TMVR in intermediate surgical risk patients is supported by an FDA analysis combining real-world registry and prospective cohort data. While no comparator arm was included, outcomes were benchmarked against historical surgical standards and predefined threshold levels. The evaluation met both FDA-defined performance goals for mortality and stroke, with additional improvements observed across functional status, quality of life, and MR severity. Adverse event rates were low and appeared with similar rates to higher surgical risk patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

The evidence for transcatheter mitral valve-in-ring replacement (TMViR) consists primarily of prospective registries, retrospective cohort studies, and single-arm observational studies evaluating patients with failed prior surgical mitral valve repair and annuloplasty rings. Published evidence from the MITRAL Trial, VIVID Registry, and other multicenter registries has demonstrated high rates of technical success, improvements in New York Heart Association functional class, reduction in mitral regurgitation severity, and improvements in patient-reported quality-of-life measures following TMViR. However, the available evidence is limited by the absence of randomized controlled trials, reliance on highly selected patient populations, variability in procedural approaches and devices used, and potential selection bias inherent to noncomparative study designs. Although

comparative studies have included small numbers of valve-in-ring patients, outcomes have generally not been reported separately from valve-in-valve populations, limiting interpretation of the independent effectiveness and safety of TMViR. Long-term durability data remain limited, and comparative evidence against redo surgical mitral valve repair or replacement is insufficient to determine whether TMViR improves net health outcomes relative to established surgical alternatives. Therefore, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association for Thoracic Surgery

In 2025, the American Association for Thoracic Surgery (AATS) published an expert consensus document on the surgical management of mitral annular calcification (MAC), developed by an international panel of cardiac surgeons and structural heart interventionalists. The document acknowledges that "surgery for mitral valve disease in patients with mitral annular calcification (MAC) remains challenging," that "there is no consensus on the ideal management strategy or patient selection," and that "perioperative and periprocedural morbidity and mortality rates remain high." The panel "followed the AATS/Society of Thoracic Surgeons (STS) guidelines for developing clinical practice documents," performed a comprehensive literature review with a medical librarian, and developed recommendations using a modified Delphi method requiring 80% participation and 75% consensus for approval. The consensus classifies MAC severity by annular circumferential involvement, calcium thickness, and leaflet, trigonal, or subvalvular involvement (Table 1).

Table 1. AATS Classification of Mitral Annular Calcification

Stage	Circumferential Involvement	Thickness, mm	Leaflet, Trigonal, or Subvalvular Involvement
Mild	<180° of the annulus	<5	No trigonal, leaflet, or subvalvular extension

Moderate	180-270° of the annulus	5-10	One leaflet, or posterior trigonal involvement without subvalvular extension
Severe	>270° of the annulus	>10	Both leaflets, anterior commissure, or subvalvular extension

With respect to transcatheter therapy, the panel concluded that "TMVR and hybrid transcatheter mitral valve replacement techniques with a multidisciplinary heart team approach are reasonable in selected high-risk patients with severe MAC" (COR IIa, LOE B-NR), and that "patients with MAC and mitral stenosis who remain symptomatic despite medical management, and who are inoperable or are at prohibitive anatomical surgical risk, should be considered for TMVR" (COR IIa, LOE B-NR). Selected recommendations relevant to transcatheter mitral valve intervention and patient selection are shown in Table 2.

Table 2. AATS 2025 Recommendations Relevant to Transcatheter Mitral Valve Intervention in Mitral Annular Calcification

Recommendation	COR	LOE
Patient selection, evaluation, and indications for intervention		
In patients with MAC who are undergoing mitral valve intervention, the STS predicted risk of mortality and morbidity does not fully capture the risk of surgery or intervention; therefore, evaluation by a multidisciplinary heart team is essential.	I (Strong)	C-EO
All cases of moderate and severe MAC in high-risk patients with MV disease should be evaluated by a multispecialty heart valve team that includes (and is not limited to) a cardiac surgeon and a structural heart cardiologist.	I (Strong)	C-LD
Preoperative TEE should be performed in all patients who are being considered for a transcatheter or hybrid intervention.	I (Strong)	C-EO
In addition to echocardiography, CT imaging should be performed in all MAC patients to adequately assess MAC extent and distribution for operative planning.	I (Strong)	C-EO

In asymptomatic or mildly symptomatic patients (New York Heart Association class I or II) with significant mitral valve disease and severe MAC, the risk of mitral intervention may be carefully weighed against watchful waiting and GDMT.	IIb (Weak)	C-LD
In patients with a limited life expectancy due to non-cardiac pathologies, marked frailty, or those who are unlikely to see symptomatic benefit, mitral valve intervention may be futile.	IIb (Weak)	B-NR
Transcatheter mitral valve intervention		
TMVR and HTMVR techniques with a multidisciplinary heart team approach are reasonable in selected high-risk patients with severe MAC.	IIa (Moderate)	B-NR
Patients with MAC and mitral stenosis who remain symptomatic despite medical management, and who are inoperable or are at prohibitive anatomical surgical risk, should be considered for TMVR.	IIa (Moderate)	B-NR
Symptomatic patients with MAC and severe mitral regurgitation who have acceptable MV area but are at high surgical risk may be considered for transcatheter edge-to-edge repair (TEER).	IIb (Weak)	C-LD
Symptomatic patients with MAC and severe mitral regurgitation who are high surgical risk and are likely to develop severe mitral stenosis with TEER can be considered for TMVR.	IIa (Moderate)	C-LD
Surgical MVR can be considered in patients with LVOT obstruction after TMVR.	IIa (Moderate)	C-EO
In case of PVL after mitral replacement in the setting of MAC, transcatheter procedure can be effective.	IIa (Moderate)	C-LD

COR: class of recommendation (I, strong; IIa, moderate, in favor; IIb, weak, may be considered); LOE: level of evidence (B-NR, moderate-quality evidence from nonrandomized studies; C-LD, limited data; C-EO, consensus of expert opinion). CT: computed tomography; GDMT: guideline-directed medical therapy; HTMVR: hybrid transcatheter mitral valve replacement; LVOT: left ventricular outflow tract; MAC: mitral annular calcification; MR: mitral regurgitation; MS: mitral stenosis; MV: mitral valve; MVR: mitral valve replacement; PVL: paravalvular leak; STS: Society

of Thoracic Surgeons; TEER: transcatheter edge-to-edge repair; TEE: transesophageal echocardiography; TMVR: transcatheter mitral valve replacement.

AATS notes: "Given the high risk of mitral stenosis after TEER in MAC patients, TMVR can be considered a more definitive treatment option. However, in patients with MAC, procedural complications may be more likely with TMVR, as evidenced by these patients' nontrivial 2-year mortality rate of nearly 40%. Therefore, a heart team approach should be followed in determining the ideal treatment option in these patients, including medical management."

American College of Cardiology and American Heart Association
In 2020, the American College of Cardiology and American Heart Association presented updated expert consensus on the management of mitral regurgitation (MR). The recommendations are as follows: "At present, transcatheter mitral repair using an edge-to-edge clip device can be considered for the treatment of patients with primary MR and severe symptoms who are felt to be poor surgical candidates. Surgical or transcatheter treatment for secondary MR is undertaken only after appropriate medical and device therapies have been instituted and optimized, as judged by the multidisciplinary team with input from a cardiologist with experience managing heart failure and MR."

Also 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 M-TEER 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. Individuals who have prosthetic valve stenosis are recommended to be offered revision surgery, but for severely symptomatic patients who are at high risk for surgery, a transcatheter aortic valve-in-valve procedure may be reasonable (B level of evidence, moderate class of recommendation); no recommendation is given regarding mitral valve-in-valve procedures. Relevant recommendations on interventions for primary and secondary MR, and prosthetic valve stenosis are shown in Table 3.

Table 3. Recommendations on Interventions for Primary and Secondary Mitral Regurgitation

Recommendation	COR	LOE
Primary MR		
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	1 (Strong)	B-NR[1]

when the anatomic cause of MR is a degenerative disease, if a successful and durable repair is possible		
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 durable 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	2a (Moderate)	B-NR[1]
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 durable repair	2b (Weak)	C-LD[2]
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	2a (Moderate)	B-NR[1]
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 durable and successful repair is likely	2b (Weak)	B-NR[1]
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	3:Harm (Strong)	B-NR[1]
Secondary MR		
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	2a (Moderate)	B-R[3]
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	2a (Moderate)	B-NR[1]
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	2b (Weak)	B-NR[1]

therapy for associated AF or other comorbidities (Stage D), mitral valve surgery may be considered		
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	2b (Weak)	B-NR[1]
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 replacement may be reasonable to choose over downsized annuloplasty repair	2b (Weak)	B-R[3]
Intervention for Prosthetic Valve Stenosis		
In patients with symptomatic severe stenosis of a bioprosthetic or mechanical prosthetic valve, repeat surgical intervention is indicated unless the surgical risk is high or prohibitive	1 (Strong)	B-NR[1]
For severely symptomatic patients with bioprosthetic aortic valve stenosis and high or prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a comprehensive valve center	2a (Moderate)	B-NR[1]
For patients with significant bioprosthetic valve stenosis attributable to suspected or documented valve thrombosis, oral anticoagulation with a VKA is reasonable	2a (Moderate)	B-NR[1]

Source: Adatped from Otto et al (2020).
[1]Moderate, nonrandomized; [2]Limited data; [3]Moderate, 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; ViV: valve-in-valve; VKA, vitamin K antagonist.

American College of Cardiology, American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons
The American College of Cardiology, American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons (2014) issued a position statement on transcatheter therapies for MR. This statement outlined critical components for successful transcatheter MR therapies and recommended ongoing research and inclusion of all patients treated with transcatheter MR therapies in a disease registry.

The European Society of Cardiology and the European Association for Cardio-Thoracic Surgery

The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) issued guidelines on the management of valvular heart disease in 2025 which are summarized in Table 4:

Table 4. 2025 ESC/EACTS Recommendations Relevant to Mitral Valve Interventions

Recommendation		
Primary MR	Class	Level
"MV repair is the recommended surgical technique to treat patients with severe PMR when the result is expected to be durable"	I	B
"MV surgery is recommended in symptomatic patients with severe PMR considered operable by the Heart Team"	I	B
"MV surgery is recommended in asymptomatic patients with severe PMR and LV dysfunction (LVESD ≥40 mm or LVESDi ≥20 mm/m2 or LVEF ≤60%)"	I	B
"Surgical MV repair is recommended in low-risk asymptomatic patients with severe PMR without LV dysfunction (LVESD <40 mm, LVESDi <20 mm/m2, and LVEF >60%) when a durable result is likely, if at least three of the following criteria are fulfilled: AF; SPAP at rest >50 mmHg; LA dilatation (LAVI ≥60 mL/m2 or LA diameter ≥55 mm); concomitant secondary TR ≥ moderate"	I	B
"MV surgery should be considered in asymptomatic patients with severe PMR without LV dysfunction (LVESD <40 mm, LVESDi <20 mm/m2, and LVEF >60%) in the presence of PH (SPAP at rest >50 mmHg, or AF secondary to MR)"	IIa	B
"Surgical MV repair should be considered in low-risk asymptomatic patients with severe PMR without LV dysfunction (LVESD <40 mm, LVESDi <20 mm/m2, and LVEF >60%) in the presence of significant LA dilatation (LAVI ≥60 mL/m2 or LA diameter ≥55 mm) when performed in a Heart Valve Centre and a durable repair is likely"	IIa	B
"TEER should be considered in symptomatic patients with severe PMR who are anatomically suitable and at high surgical risk according to the Heart Team"	IIa	B
"Minimally invasive MV surgery may be considered at experienced centres to reduce the length of stay and accelerate recovery"	IIb	B
Secondary MR	Class	Level
Severe atrial secondary mitral regurgitation		
"MV surgery, surgical AF ablation, if indicated, and LAAO should be considered in symptomatic patients with severe atrial SMR under optimal medical therapy"	IIa	B

"TEER may be considered in symptomatic patients with severe atrial SMR not eligible for surgery after optimization of medical therapy including rhythm control, when appropriate"	IIb	B
Ventricular secondary mitral regurgitation and concomitant coronary artery disease		
"MV surgery is recommended in patients with severe ventricular SMR undergoing CABG"	I	B
"MV surgery may be considered in patients with moderate SMR undergoing CABG"	IIb	B
"PCI followed by TEER after re-evaluation of MR may be considered in symptomatic patients with chronic severe ventricular SMR and non-complex CAD"	IIb	C
Severe ventricular secondary mitral regurgitation without concomitant coronary artery disease		
"TEER is recommended to reduce HF hospitalizations and improve quality of life in haemodynamically stable, symptomatic patients with impaired LVEF (<50%) and persistent severe ventricular SMR, despite optimized GDMT and CRT (if indicated), fulfilling specific clinical and echocardiographic criteria"	I	A
"TEER may be considered for symptom improvement in selected symptomatic patients with severe ventricular SMR not fulfilling the specific clinical and echocardiographic criteria, after careful evaluation of LVAD or HTx"	IIb	B
"MV surgery may be considered in symptomatic patients with severe ventricular SMR without advanced HF who are not suitable for TEER"	IIb	C
Degenerative mitral stenosis with mitral annular calcification		
"TMVI may be considered in symptomatic patients with extensive MAC and severe MV dysfunction at experienced Heart Valve Centres with expertise in complex MV surgery and transcatheter interventions."	IIb	C
Biological heart valve failure / prosthetic valve dysfunction		
"Reintervention is recommended in symptomatic patients with significant valve dysfunction not attributable to valve thrombosis."	I	C
"Transcatheter transvenous mitral or tricuspid valve-in-valve implantation should be considered in patients with significant valve dysfunction at intermediate or high surgical risk, if the anatomy is suitable."	IIa	B

AF: atrial fibrillation; BHV: biological heart valve; CABG: coronary artery bypass grafting; CAD: coronary artery disease; CRT: cardiac resynchronization therapy; GDMT: guideline-directed medical therapy; HF: heart failure; HTx: heart transplantation; LAAO: left atrial appendage occlusion; LV: left ventricular; LVAD: left ventricular assist device; LVEF: left ventricular ejection fraction; LVOT: left ventricular outflow tract; MAC: mitral annular calcification; MR: mitral

regurgitation; MS: mitral stenosis; MV: mitral valve; PCI: percutaneous coronary intervention; PMC: percutaneous mitral commissurotomy; PVL: paravalvular leak; SMR: secondary mitral regurgitation; TEER: transcatheter edge-to-edge repair; TMVI: transcatheter mitral valve implantation.

With respect to degenerative MS with MAC, the guideline states that "Treatment options (including transcatheter and surgical approaches) are high-risk procedures and evidence from RCTs is lacking." The guideline notes that "Degenerative MS is not amenable to percutaneous mitral commissurotomy because commissural fusion is absent." For symptomatic high-risk patients with suitable anatomy, the guideline states that "transcatheter implantation of a TAVI prosthesis in the mitral position is feasible but associated with frequent complications, including LVOT obstruction, valve embolization, stroke, and haemolysis due to paravalvular leak." The guideline further states that "The use of dedicated TMVI devices is therefore encouraged because it appears to be safer" and that "Heart Team evaluation should guide the choice of treatment avoiding futility, because mortality remains high, even after successful treatment (10% to 30% within 1 year)."

Heart Valve Collaboratory
In 2023, the Heart Valve Collaboratory published a position statement on the diagnosis, classification, and management of MAC. The authors note that mitral annular calcium "with severe mitral valvular dysfunction presents a complex problem, as valve replacement, either surgical or transcatheter, is challenging because of anatomy, technical considerations, concomitant comorbidities, and advanced age." The statement proposes a MAC severity grading system that integrates transthoracic/transesophageal echocardiographic and cardiac CT features, classifying MAC as mild (<180° annular circumference of calcium by echocardiography, or a CT MAC score ≤ 3), moderate (180°-270° circumference, or a CT MAC score of 4-6), or severe (≥ 270° circumference or ventricular wall calcification, or a CT MAC score ≥ 7, ventricular wall calcification, or calcium volume >1,000 mm3). The CT-based MAC score is derived from four anatomical features (average annular calcium thickness, calcium distribution around the annular circumference, trigone calcification, and mitral leaflet calcification), with a total score of ≤ 3 points indicating mild, 4-6 points moderate, and ≥ 7 points severe MAC. The statement also describes a green-light/yellow-light/red-light framework characterizing anatomical and clinical features as favorable, challenging, or prohibitive for surgical or transcatheter mitral valve intervention. The working group did not issue graded (class of recommendation/level of evidence) recommendations. Suitability considerations for standard surgical mitral valve replacement and the 2 U.S. FDA-approved TMVR devices are summarized in Table 5.

Table 5. Suitability Considerations for Surgery and Transcatheter Mitral Valve Replacement Devices in Mitral Annular Calcification

Suitability Category	Standard Surgical MVR	Transseptal ViMAC (SAPIEN M3)	Transapical TMVR (Tendyne)

Suitable risk	Medical: Minimal, well-compensated comorbidities; minimal (0-1/4) frailty Anatomy: CT-based MAC score <4; calcium thickness ≤5 mm; no calcium penetration into the epicardial fat Cardiac: No severe diastolic dysfunction	Medical: Not significant comorbidities Anatomy: CT MAC score <4; neo-LVOT >200 mm²; no commissural jet, flail, or prolapse; interatrial septal anatomy favorable for transseptal access; intercommissural diameter <35 mm Cardiac: No significant diastolic dysfunction, RV dysfunction, untreated CAD, or other valvular pathology	Medical: No significant comorbidities Anatomy: Mitral annular area (650-1,540 mm²) or perimeter (90-144 mm) Cardiac: No significant diastolic dysfunction, RV dysfunction, untreated CAD, or other valvular pathology
High risk	Medical: Moderate comorbiditiesb; prior chest radiation; STS score for MVR >6; frailty (≥2/4); chronic immunosuppression Anatomy: CT-based MAC score ≥4; calcium thickness >5 mm at any point; calcium extending into epicardial fat or myocardium; significant calcium located at lateral trigone or in aortomitral curtain Cardiac: Diastolic dysfunction; other VHD requiring surgery; need for surgical lateral or inferior wall revascularization; PASP ≥70 mm Hg but <2/3 systemic	Medical: Moderate comorbiditiesb Anatomy: CT-based MAC score ≥4; neo-LVOT <200 mm²; commissural jet, flail, or prolapse not causing main jet of MR; lipomatous interatrial septum; low transseptal height <3 cm; intercommissural diameter >35 mm Cardiac: Diastolic dysfunction; mild to moderate RV dysfunction; untreated CAD; untreated moderate AS	Medical: Moderate comorbiditiesb Anatomy: Neo-LVOT <200 mm²; mitral annulus (area <650 or >1,540 mm²) Cardiac: Diastolic dysfunction; mild to moderate RV dysfunction; untreated CAD; untreated moderate AS
Extreme risk	Medical: Severe comorbiditiesa; frailty (3-	Medical: Severe comorbiditiesa	Medical: Severe comorbiditiesa

	4/4); STS score ≥8; chronic immunosuppression; significant neurodegenerative disease Anatomy: ~270° of calcification; calcium width/thickness >10 mm in any area Cardiac: Severe RV dysfunction; severe LV dysfunction; PASP >70 mm Hg and >2/3 systemic; infiltrative cardiomyopathy (ie, amyloidosis)	Anatomy: Skirt neo-LVOT <150 mm² after septal reduction strategies; commissural jet, flail, or prolapse as main cause of MR; anatomy that precludes transseptal access; intercommissural diameter >45 mm; calcium spicule protruding into the annulus or LV cavity that would interfere with dock delivery Cardiac: Severe RV dysfunction; severe untreated AS	Anatomy: Severe mitral stenosis with extensive leaflet calcium; skirt neo-LVOT <150 mm² after septal reduction strategies; mitral annulus (area <650 or >1,540 mm²) Cardiac: Severe RV or LV dysfunction; severe untreated AS; LV apex unsuitable for access

a Severe comorbidities: end-stage renal disease, severe lung pathology, severe liver pathology, extreme frailty, chronic immunosuppression, and dementia. b Moderate comorbidities: chronic kidney disease not requiring hemodialysis, lung disease not requiring oxygen therapy at home, mild to moderate liver pathology, moderate frailty, and mild dementia.

AS: aortic stenosis; CAD: coronary artery disease; CT: computed tomographic; LV: left ventricular; LVOT: left ventricular outflow tract; MAC: mitral annular calcium; MR: mitral regurgitation; RV: right ventricular; TMVR: transcatheter mitral valve replacement; ViMAC: valve-in-mitral annular calcification.

National Institute for Health and Care Excellence
The NICE guideline on heart valve disease management (2021) makes the following recommendations related to TMVR:

- "1.5.10 - Consider transcatheter edge-to-edge repair, if suitable, for adults with severe primary mitral regurgitation and symptoms, if surgery is unsuitable.
- 1.5.14 - Consider transcatheter mitral edge-to-edge repair for adults with heart failure and severe secondary mitral regurgitation, if surgery is unsuitable and they remain symptomatic on medical management."

Another NICE guideline was issued in 2021 on the use of transapical transcathter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis:

- "1.1 - Evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis is adequate and shows some serious but well-recognised complications. Evidence on its efficacy is limited in quality.

So, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

- "1.4 - Patient selection should be done by a multidisciplinary team which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging, and where appropriate, a cardiac anaesthetist and a specialist in medicine for older people. The multidisciplinary team should determine the risk level for each patient and the device most suitable for them."
- "1.6 - The procedure is technically challenging and should only be done in specialised centres, and only by clinical teams with special training and experience in complex endovascular cardiac interventions, including regular experience in transcatheter valve implantation procedures. Centres doing these procedures should have cardiac surgical support for emergency treatment of complications and subsequent patient care."
- "1.7 - NICE encourages further research into transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. Studies should include details on patient selection, type and size of valve used, functional outcomes (New York Heart Association functional class, mitral valve regurgitation), quality of life, patient-reported outcome measures, survival and complications. Studies should report long-term follow up of clinical outcomes and valve durability. NICE may update this guidance on publication of further evidence."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The Centers for Medicare & Medicaid Services issued a national coverage decision for the use of TMVR in 2015, which was updated in 2023.

The Centers for Medicare & Medicaid Services determined that it would cover M-TEER under Coverage with Evidence Development for the treatment of symptomatic moderate-to-severe or severe functional (secondary) MR or significant symptomatic degenerative (primary) MR when all of the following conditions are met:

"1. The procedure is furnished with a [M-TEER] system that has received FDA [Food and Drug Administration] premarket approval (PMDA).
2. The patient (preoperatively and postoperatively) is under the care of a heart team...
3. Each patient's suitability for surgical mitral valve repair, [M-TEER], or palliative therapy must be evaluated, documented...
4. An interventional cardiologist or cardiac surgeon from the heart team must perform the mitral valve [M-TEER]...
5. Mitral valve [M-TEER] must be furnished in a hosptial with appropriate infrastructure and experience...
6. The heart team and hospital are participating in a prospective, national, audited registry...
7. The registry shall collect all data necessary and have a written executable analysis plan..."

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01626079[a]	Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (The COAPT Trial) and COAPT CAS (COAPT)	776	Jul 2024 (unknown)
NCT04198870[a]	Percutaneous MitraClip Device or Surgical Mitral Valve REpair in PAtients With Primary MItral Regurgitation Who Are Candidates for Surgery (REPAIR MR)	500	Dec 2035
NCT05090540	Transcatheter Edge to Edge Mitral Valve Repair Versus Standard Surgical Mitral Valve Operation for Secondary Mitral Regurgitation	600	Dec 2025
NCT05051033	Percutaneous or Surgical Repair In Mitral Prolapse And Regurgitation for ≥65 Year-Olds (PRIMARY)	450	Nov 2030
NCT05021614[a]	Evaluation of the Efficacy and Safety of the Transcatheter Mitral Valve Repair System in Patients With Moderate and Above Degenerative Mitral Regurgitation at High Surgical Risk	150	Sep 2027
NCT04734756[a]	A Prospective, Multicenter, Objective Performance Criteria Study to Evaluate the Safety and Effectiveness of Dragonfly Transcatheter Mitral Valve Repair System for the Treatment of Degenerative Mitral Regurgitation (DMR) Subjects	120	May 2027
NCT04733404[a]	A Prospective, Multicenter, Objective Performance Criteria Study to Evaluate the Safety and Effectiveness of Dragonfly Transcatheter Mitral Valve Repair System for the Treatment of Functional Mitral Regurgitation (FMR) Subjects	120	Sep 2027

NCT04430075[a]	Transcatheter Repair of Mitral Regurgitation With Edwards PASCAL Transcatheter Valve Repair System: A European Prospective, Multicenter Post Market Clinical Follow-Up (PMFC)	1000	Mar 2031
NCT03706833[a]	Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP IID/IIF): A Prospective, Multicenter, Randomized, Controlled Pivotal Trial to Evaluate the Safety and Effectiveness of Transcatheter Mitral Valve Repair With the Edwards PASCAL Transcatheter Valve Repair System Compared to Abbott MitraClip in Patients With Mitral Regurgitation	1247	Jun 2031
NCT05496998[a]	Transcatheter Mitral Valve Replacement With the Medtronic Intrepid™ TMVR Transfemoral System in Patients With Severe Symptomatic Mitral Regurgitation - APOLLO-EU Trial	400	Dec 2038
NCT05455489	GISE Registry of Transcatheter Treatment of Mitral Valve Regurgitation With the MitraClip G4	264	Aug 2029
NCT03271762	Multicentre and Randomized Study of MITRACLIP® Transcatheter Mitral Valve Repair in Patients With Severe Primary Mitral Regurgitation Eligible for High-risk Surgery	330	Jan 2028
NCT04402931	Randomized Trial of Transcatheter Valve-in-Valve Intervention vs Redo Surgery for the Treatment of Structural Mitral Bioprosthetic Dysfunction	150	Aug 2025
NCT03193801	PARTNER 3 Trial - SAPIEN 3 Transcatheter Heart Valve Implantation in Patients With a Failing Mitral Bioprosthetic Valve	53	Aug 2031
NCT04177394	A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System	1164	Mar 2028
NCT06634121	Efficacy of Mitraclip Vs. PASCAL for the Treatment of Mitral Regurgitation in an All-comer Population	180	Apr 2028

NCT03433274	Clinical Trial to Evaluate the Safety and Effectiveness of Using the Tendyne Transcatheter Mitral Valve System for the Treatment of Symptomatic Mitral Regurgitation	103	June 2028
NCT04097145	A Prospective, Multicenter, Randomized, Controlled Pivotal Trial to Evaluate the Safety and Effectiveness of Transcatheter Tricuspid Valve Repair With the Edwards PASCAL Transcatheter Valve Repair System and Optimal Medical Therapy (OMT) Compared to OMT Alone in Patients With Tricuspid Regurgitation	870	Dec 2031
NCT05051033	Percutaneous or Surgical Repair In Mitral Prolapse And Regurgitation for ≥60 Year-olds (PRIMARY)	450	Nov 2030
Unpublished			
NCT05332782	Outcomes of Patients tReated with Mitral Transcatheter Edge-to-edge Repair for Primary Mitral Regurgitation Registry (PRIME-MR)	2000	Jan 2026 (unknown status)
NCT04009434	Treatment of Concomitant Mitral Regurgitation by Mitral Valve Clipping in Patients With Successful Transcatheter Aortic Valve Implantation	1162	Aug 2023 (unknown status)
NCT05417945[a]	A Prospective, Multicenter Study to Evaluate the JensClip Transcatheter Valve Repair System	124	Dec 2024 (unknown status)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.
[b]Primary results have been published, long-term follow-up ongoing

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Policy History

Original Effective Date: 02/17/2016
Current Effective Date: 12/01/2026

02/04/2016	Medical Policy Committee review
02/17/2016	Medical Policy Implementation Committee approval. New Policy
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
02/02/2017	Medical Policy Committee review

02/15/2017 Medical Policy Implementation Committee approval. No change to coverage.
02/01/2018 Medical Policy Committee review
02/21/2018 Medical Policy Implementation Committee approval. No change to coverage.
02/07/2019 Medical Policy Committee review
02/20/2019 Medical Policy Implementation Committee approval. Degenerative mitral regurgitation was replaced with primary mitral regurgitation and functional mitral regurgitation was replaced with secondary mitral regurgitation including the policy statement to be in consistent with language used in the guidelines.
08/01/2019 Medical Policy Committee review
08/14/2019 Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company may consider transcatheter mitral valve repair with a device approved by the U.S. Food and Drug Administration 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 to be eligible for coverage**" Added Policy Guidelines section.
08/06/2020 Medical Policy Committee review
08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021 Medical Policy Committee review
08/11/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022 Medical Policy Committee review
08/10/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023 Medical Policy Committee review
08/09/2023 Medical Policy Implementation Committee approval. No change to coverage.
08/01/2024 Medical Policy Committee review
08/14/2024 Medical Policy Implementation Committee approval. Policy updated with literature review through March 6, 2024; title changed to 'Transcatheter Mitral Valve Repair or Replacement'; new indication for transseptal valve-in-valve replacement; references added. Policy statement added:

Transcatheter mitral valve-in-valve replacement (TMViVR) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) is considered medically necessary for individuals when all of the following conditions are present:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve; AND
- New York Heart Association heart failure class II, III, or IV symptoms; AND
- Individual is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); OR individual is an operable candidate but is considered at increased surgical risk for open surgery, as documented by at least 2 cardiac specialists (including a cardiac surgeon); OR individual is considered at increased surgical risk for open surgery (eg, repeat sternotomy) due to a history of congenital vascular

anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon). Title changed from "Transcatheter Mitral Valve Repair" to "Transcatheter Mitral Valve Repair or Replacement."

08/07/2025 Medical Policy Committee review

08/13/2025 Medical Policy Implementation Committee approval. Criteria bullet revised to read: "Individual is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); OR individual is an operable candidate but is considered at an intermediate to prohibitive surgical risk for open surgery, as documented by at least 2 cardiac specialists (including a cardiac surgeon); OR individual is considered at an intermediate to prohibitive surgical risk for open surgery (eg, repeat sternotomy) due to a history of congenital vascular anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon) (see Policy Guidelines section)."

08/06/2026 Medical Policy Committee review

08/12/2026 Medical Policy Implementation Committee review

08/20/2026 Medical Quality Management Committee approval. Decided to pull policy and move to September.

09/03/2026 Medical Policy Committee review

09/09/2026 Medical Policy Implementation Committee review

09/17/2026 Medical Quality Management Committee approval. Added "Based on review of available data, the Company may consider mitral transcatheter edge-to-edge repair (M-TEER) for treatment of primary mitral regurgitation" to be eligible with criteria. Added "Based on review of available data, the Company may consider mitral transcatheter edge-to-edge repair (M-TEER) for treatment of secondary (functional) mitral regurgitation" to be eligible with criteria. Added "Based on review of available data, the Company may consider valve-in-valve transcatheter mitral valve replacement (ViV-TMVR)" to be eligible for coverage with criteria. Added "The use of mitral transcatheter edge-to-edge repair (M-TEER) for treatment of primary or secondary (functional) mitral regurgitation when patient selection criteria are not met is considered not medically necessary." Added "The use of valve-in-valve transcatheter mitral valve replacement (ViV-TMVR) when patient selection criteria are not met is considered not medically necessary."Added "Based on review of available data, the Company considers valve-in-ring transcatheter mitral valve replacement (ViR-TMVR, e.g., SAPIEN 3) for all indications to be investigational." Added "Based on review of available data, the Company considers native transcatheter mitral valve replacement (TMVR) (e.g., Tendyne™‡ and SAPIEN M3™‡ systems) for all indications, including treatment of severe mitral annular calcification (ViMAC), to be investigational." Title changed from "Transcatheter Mitral Valve Repair or Replacement" to "Transcatheter Mitral Valve Replacement or Edge to Edge Repair."

Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0345T, 0483T, 0484T, 0544T, 33418, 33419
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);

2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.