Medical Policy
Transcatheter Mitral Valve Repair

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Policy Number: 692
BCBSA Reference Number: 2.02.30
NCD/LCD: National Coverage Determination (NCD) for Transcatheter Mitral Valve Repair (TMVR) (20.33)

Related Policies
Transcatheter Pulmonary Valve Implantation, #403
Transcatheter Aortic-Valve Implantation for Aortic Stenosis, #392

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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, degenerative mitral regurgitation who are considered at prohibitive risk for open surgery.

“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.

Transcatheter mitral valve repair is considered INVESTIGATIONAL in all situations.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determination (NCD) for Transcatheter Mitral Valve Repair (TMVR) (20.33)

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>N/A</th>
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<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
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</tr>
<tr>
<td>Medicare HMO Blue&lt;sup&gt;SM&lt;/sup&gt;</td>
<td>N/A</td>
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<tr>
<td>Medicare PPO Blue&lt;sup&gt;SM&lt;/sup&gt;</td>
<td>N/A</td>
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CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33418</td>
<td>Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis</td>
</tr>
<tr>
<td>33419</td>
<td>Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>0345T</td>
<td>Transcatheter mitral valve repair percutaneous approach via the coronary sinus</td>
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</table>

ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>ICD-10-PCS procedure codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>02RG3JZ</td>
<td>Replacement of Mitral Valve with Synthetic Substitute, Percutaneous Approach</td>
</tr>
<tr>
<td>02RG4JZ</td>
<td>Replacement of Mitral Valve with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02QG3ZZ</td>
<td>Repair Mitral Valve, Percutaneous Approach</td>
</tr>
<tr>
<td>02QG4ZZ</td>
<td>Repair Mitral Valve, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>02UG3JZ</td>
<td>Supplement Mitral Valve with Synthetic Substitute, Percutaneous Approach</td>
</tr>
<tr>
<td>02UG4JZ</td>
<td>Supplement Mitral Valve with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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</tbody>
</table>

Description

**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.1 MR can result from a heterogeneous set of disease processes that may affect 1 or more parts of the mitral valve (MV) complex. The functional anatomy of the MV complex includes the left ventricular (LV) myocardium, the subvalvular apparatus including the papillary muscles and chordae tendineae, the mitral annulus, the MV...
leaflets, and the left atrium. The underlying cause of MR and the portion of the MV complex involved determine the underlying treatment strategy.

MR is classified into degenerative and functional MV disease. In degenerative mitral regurgitation (DMR), disease results from a primary structural abnormality of the MV complex. Common causes of DMR include MV prolapse syndrome with subsequent myxomatous degeneration, rheumatic heart disease, coronary artery disease, infective endocarditis, and collagen vascular disease. In contrast, in functional mitral regurgitation (FMR), the primary abnormality is a dilated LV due to ischemic or dilated cardiomyopathy, which leads to secondary dilatation of an anatomically normal MV. 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).

MR with accompanying valvular incompetence leads to LV volume overload with secondary ventricular remodeling, myocardial dysfunction, and left heart failure. Clinical signs and symptoms of dyspnea and orthopnea may also present in patients with valvular dysfunction. Acute MR can result from conditions such as ruptured chordae tendineae or infectious endocarditis; and when severe, it can present with simultaneous shock and pulmonary congestion. Chronic MR may remain asymptomatic over a long period of time due to compensatory LV hypertrophy secondary to the LV overload. This leads to increased LV end-diastolic volume and, in turn, increased stroke volume (to restore forward cardiac output) and increased LV and left atrial size (to accommodate the regurgitant volume at lower filling pressure). Eventually, prolonged volume overload leads to contractile dysfunction, with increased end-systolic volume, further LV dilatation, and increased LV filling pressure. These changes ultimately lead to reduced forward cardiac output and signs and symptoms of pulmonary congestion.

Standard Management

Medical Management
Medical management has a role in a subset of MR cases. Among patients with chronic DMR, there is no generally accepted medical management. In FMR, medical management plays a much greater role because the underlying pathophysiology is related to LV dysfunction and dilatation. Primary treatment of the LV systolic dysfunction with angiotensin-converting enzyme inhibitors, β-blockers, and biventricular pacing can reduce LV pressures, decrease LV dilatation, improve cardiac output, and thus ameliorate clinical symptoms.

Surgical Management
In patients with symptoms of MR with preserved LV function (DMR), surgery is the main therapy. In most cases, repair of the MV 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 for the surgical management of MV, which are outlined in Table 1.

Table 1. Guidelines on Mitral Value Surgery

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
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<tbody>
<tr>
<td>MV surgery is recommended for the symptomatic patient with acute severe MR.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>MV surgery is beneficial for patients with chronic severe MR and NYHA functional class II, III, or IV symptoms in the absence of severe LV dysfunction (severe LV dysfunction is defined as ejection fraction less than 0.30) and/or end-systolic dimension greater than 55 mm.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>MV surgery is beneficial for asymptomatic patients with chronic severe MR and mild-to-moderate LV dysfunction, ejection fraction 0.30 to 0.60, and/or end systolic dimension greater than or equal to 40 mm.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>MV repair is recommended over MV replacement in the majority of patients with severe chronic MR who require surgery, and patients should be referred to surgical centers experienced in MV repair.</td>
<td>I</td>
<td>C</td>
</tr>
</tbody>
</table>
MV repair is also reasonable for asymptomatic patients with chronic severe MR with preserved LV function … in whom the high likelihood of successful MV repair without residual MR is greater than 90%.

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
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<tr>
<td>IIA</td>
<td>B</td>
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</table>

MV surgery is reasonable for asymptomatic patients with chronic severe MR, preserved LV function, and new onset of atrial fibrillation

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
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<tr>
<td>IIA</td>
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MV surgery is reasonable for asymptomatic patients with chronic severe MR,* preserved LV function, and pulmonary hypertension….

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
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<td>IIA</td>
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MV surgery is reasonable for patients with chronic severe MR due to a primary abnormality of the mitral apparatus and NYHA functional class III–IV symptoms and severe LV dysfunction … in whom MV repair is highly likely

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
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<tbody>
<tr>
<td>IIA</td>
<td>C</td>
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</table>

COR: class of recommendation; LOE: level of evidence; LV: left ventricular; MR: mitral regurgitation; MV: mitral valve; NYHA: New York Heart Association.

Standard open MV repair includes quadrangular leaf resection (if MV prolapse is present), transposition of normal valve chords to other areas of prolapsing leaflet, and a remodeling annuloplasty with a ring prosthesis. Multiple types of annuloplasty rings and bands specific to the underlying cause of the MR are commercially available.2 Introduced in the 1990s, the edge-to-edge approximation technique (Alfieri repair), typically combined with an annuloplasty, involves suturing the anterior and posterior MV leaflets together at their midpoint, creating a double-orifice MV.2,5

However, there are limitations to the open surgical approaches for MV repair. While surgical MV repair is durable, its use is limited by the requirement for thoracotomy and cardiopulmonary bypass, which may not be tolerated by patients who are elderly or debilitated due to their underlying cardiac disease or other conditions. In a 2007 study of 396 patients in Europe with severe, symptomatic MR, Mirabel et al found that about half of patients did not undergo surgical repair, specifically 56% of patients with DMR and 32% with FMR did not.6 Older age, impaired LV ejection fraction, and presence of comorbidities were all associated with the decision not to operate. In a single-center evaluation of 5737 patients with severe MR in the United States, Goel et al (2014) found that 53% of patients did not have MV surgery performed.7 Compared with those who received surgery, patients who did not had lower ejection fractions (27% vs 42%, p<0.001) and were at higher surgical risk, as judged by a higher Society of Thoracic Surgeons score (median, 5.8 vs 4.0, p<0.001). These findings suggest that there is an unmet need for less invasive procedures for MV repair.

Transcatheter MV Repair

Transcatheter approaches have been investigated to address the unmet need for less invasive MV repair, particularly among 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.1,8 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

One device that undertakes direct leaflet repair, the MitraClip Clip Delivery System (Abbott Vascular, Menlo Park, CA), has been approved through the premarket approval process by the U.S. Food and Drug Administration for use in certain patients with symptomatic MR (see Regulatory Status section). Of the transcatheter MV repair devices under investigation, MitraClip has the largest body of evidence evaluating its use and has been in use in Europe since 2008.9 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.
Other MV Repair Devices
Additional devices for transcatheater MV 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, Kirkland, WA) and the Monarc™ device (Edwards Lifesciences, Irvine, CA). 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 (AMADEUS) and the follow-up Tighten the Annulus Now (TITAN) study, with further studies planned.\textsuperscript{10} The Monarc system also involves 2 self-expanding stents connected by a nitinol bridge, with 1 end implanted in the coronary sinus via internal jugular vein and the other in the great cardiac vein. Several weeks following implantation, a 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 (EVOLUTION I) trial.\textsuperscript{11}

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

Transcatheter MV Replacement
Several devices are under development for transcatheter MV replacement, including the Endovalve™ (MicroInterventional Devices, Langhorne, PA), the CardiAQ™ (CardiAQ Valve Technologies, Irvine, CA) valve, the Cardiovalve (Valtech Cardio, Or-Yehuda, Israel), and the Fortis Transcatheter Mitral Valve (Edwards Lifesciences, Irvine, CA).

Summary
Transcatheter mitral valve repair (TMVR) is an alternative 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 anatomic 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. One device, MitraClip, has approval from the U.S. Food and Drug Administration (FDA) for the treatment of severe symptomatic MR due to a primary abnormality of the MV (degenerative mitral regurgitation [DMR]) in patients considered at prohibitive risk for surgery.

For individuals who have symptomatic DMR or functional mitral regurgitation (FMR) and are at prohibitive risk for open surgery who receive TMVR using MitraClip, the evidence includes primarily single-arm cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. Several single-arm studies have demonstrated that MitraClip implantation is feasible, with high rates (at least 70% to 90%) of short-term reductions in MR grade to 2+ or less, and a reasonable safety profile. A nonrandomized analysis matching patients in the EVEREST registries to similar non-surgically-treated patients found significantly lower 1-year morality rates in MitraClip-treated patients. However, the lack of concurrent control groups, especially in randomized trials, makes it difficult to draw conclusions on whether there is a net health benefit compared with alternative therapies in this population. There are no strong barriers to conducting controlled trials, including randomized controlled trials (RCTs) comparing MitraClip to continued medical management. The evidence is insufficient to determine the effects of the technology on health outcomes.
Clinical input supported the use of TMVR in patients with DMR considered at a prohibitive risk for open surgery, which is the FDA-approved indication for the MitraClip device. Given the lack of other treatment options for this population, the suggestive clinical evidence, and supportive clinical input, TMVR with the MitraClip may be considered medically necessary for this patient population.

For individuals who have symptomatic DMR or FMR and are surgical candidates who receive TMVR using MitraClip, the evidence includes a systematic review, an RCT, and several comparative and non-comparative cohort studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that MitraClip was noninferior to open surgery in terms of safety and effectiveness at 1-year follow-up. At 5-year follow-up, efficacy, assessed using a composite outcome, was significantly higher in the surgery group than in the MitraClip group. The RCT had some methodologic limitations, including a wide noninferiority margin and permissibility of crossing over to surgery and still considered to have a positive outcome. This single trial does not definitively demonstrate improved clinical outcomes with MitraClip compared with surgery. Additional Other RCTs are needed to corroborate these results. A subsequent nonrandomized controlled trial, which attempted to verify the findings of the RCT, did not find the same low rates of long-term MR control in MitraClip patients with an initially positive response to treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have DMR or FMR who receive TMVR using devices other than MitraClip, the evidence includes primarily noncomparative feasibility studies. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related morbidity. The body of evidence consists only of very small case series and case reports. Controlled studies, preferably RCTs, are needed to draw conclusions about the net health benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>7/2017</td>
<td>BCBSA National medical policy review. Medically necessary criteria clarified. 7/1/2017</td>
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<tr>
<td>7/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**


