MEDICAL POLICY – 2.02.30
Transcatheter Mitral Valve Repair

BCBSA Ref. Policy: 2.02.30
Effective Date: Aug 1, 2017
Last Revised: July 11, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.131 Transcatheter Pulmonary Valve Implantation
7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

The heart has four chambers, two upper and two lower. The mitral valve is between the upper and lower left chambers. After blood has been pumped from the upper left chamber to the lower left chamber, the mitral valve closes. The mitral valve is made up of small pieces of tissue called leaflets. If the leaflets don’t close properly, when the left lower chamber pumps blood out to the body, some of the blood can leak back into the upper left chamber. This is known as mitral valve regurgitation. Medication can be used to help manage the symptoms of mitral valve regurgitation. Open heart surgery is a treatment option. If a person is too sick for surgery, a nonsurgical procedure may be used to place a clip to help close the leaky mitral valve. In this procedure, a long, hollow tube (a catheter) is threaded through a specific vein into the heart. The catheter then becomes the pathway for getting the clip to the mitral valve. Imaging is used to make sure the device is correctly placed. This policy describes when transcatheter mitral valve repair is considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

Service | Medical Necessity
---|---
Transcatheter mitral valve repair | Transcatheter mitral valve repair using a device approved by the Food and Drug Administration 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 mitral valve repair surgery may be determined based on:
- The documented presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater
- The documented presence of a logistic EuroSCORE of 20% or greater.

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

Coding

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<tr>
<th>Code</th>
<th>Description</th>
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<td>CPT</td>
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<td>0345T</td>
<td>Transcatheter mitral valve repair percutaneous approach via the coronary sinus</td>
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<tr>
<td>33418</td>
<td>Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis</td>
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<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>93799</td>
<td>Unlisted cardiovascular service or procedure</td>
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</table>

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Indications for Use

The FDA summary of safety and effectiveness data (SSED) from 2013 states the indications for use below:

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR of 3+ or greater) 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 that includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

Repair Device

MitraClip® Clip Delivery System has the U.S. Food and Drug Administration (FDA) approval for the treatment of severe symptomatic degenerative mitral regurgitation (see Regulatory Status).

Evidence Review

Description

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 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. 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.
Background

*Mitral Regurgitation*

**Epidemiology and Classification**

Mitral regurgitation (MR) is a 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 can result from a heterogeneous set of disease processes that may affect 1 or more parts of the 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 left ventricle due to ischemic or dilated cardiomyopathy, which leads to secondary dilatation of an anatomically normal MV.

MR severity is classified into mild, moderate, and 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 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 present in patients with valvular dysfunction. MR can be acute or chronic. Acute MR can result from conditions such as ruptured chordae tendineae or infectious endocarditis, and when severe, 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 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 given that the underlying pathophysiology is related to LV dysfunction and dilatation. Primary treatment of the LV systolic dysfunction with angiotensin converting enzyme inhibitors, beta blockers, and biventricular pacing can reduce LV pressures, decrease LV dilatation, improve cardiac output, and thus ameliorate clinical symptoms.\(^3,4\)

**Surgical Management**

In patients with symptoms of MR with preserved LV function (DMR), surgery is the mainstay of 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 (ACC) and the American Heart Association (AHA) have issued joint guidelines for the surgical management of MV, which are outlined in Table 1.\(^3\)

### 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>
<tr>
<td>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%.</td>
<td>IIa</td>
<td>B</td>
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</tbody>
</table>
Recommendation

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>MV surgery is reasonable for asymptomatic patients with chronic severe MR, preserved LV function, and new onset of atrial fibrillation</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>MV surgery is reasonable for asymptomatic patients with chronic severe MR,* preserved LV function, and pulmonary hypertension....</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>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</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</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 chordae tendineae 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. In the 1990s, the edge-to-edge approximation technique (Alfieri repair) was introduced. Typically combined with an annuloplasty, the Alfieri repair involves suturing the anterior and posterior MV leaflets together at their midpoint, creating a double-orifice MV.

However, there are limitations to the standard approaches for MV surgery. While surgical MV repair is typically durable, its use is limited by the requirement for thoracotomy and cardiopulmonary bypass, which is particularly a concern among 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. Fifty-six percent and 32% of patients with DMR and FMR, respectively, did not undergo surgery. 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 found that 53% of patients did not have MV surgery performed. Compared with those who received surgery, patients who did not receive surgery had lower ejection fractions (27 vs 42, p<0.001) and were of 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 their...
ages 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 through indirect approaches based on the annulus’ 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 approval through FDA premarket approval process for use in certain patients with symptomatic MR (see **Regulatory Status** section). Of the transcatheter MV repair devices under investigation, the MitraClip® has the largest body of evidence evaluating its use and has been in use in Europe since 2008. The MitraClip® system is a percutaneously deployed device that approximates the open Alfieri edge-to-edge repair approach to treating MR. The delivery system consists of a delivery catheter, a steerable sleeve and the MitraClip® device, which is a 4-mm wide clip fabricated from a cobalt-chromium alloy and polypropylene fabric. The MitraClip® is deployed via a transfemoral approach, with trans-septal puncture used to access the left side of the heart and the MV. Placement of the MitraClip® leads to coapting of the mitral leaflets, thus creating a double-orifice valve.

**Other MV Repair Devices**

Additional devices for transcatheter MV repair that use various 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. The Carillon system has been evaluated in the AMADEUS (Carillon Mitral Annuloplasty Device European Union Study) and the follow-up TITAN (Tighten the Annulus Now) study, with further studies planned. The Monarc system also involves 2 self-expanding stents connected by a nitinol bridge. 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
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 transcatheter 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 of Evidence

For individuals who have symptomatic degenerative mitral regurgitation (DMR) or functional mitral regurgitation (FMR) and are at prohibitive risk for open surgery who receive transcatheter mitral valve repair (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 mitral regurgitation (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 mortality 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.
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 noncomparative 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, the efficacy of treatment, 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 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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 2.

**Table 2. Summary of Key Trials**

<table>
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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>NCT01841554</td>
<td>Cardioband With Transfemoral Delivery System</td>
<td>51</td>
<td>Jul 2016 (ongoing)</td>
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<tr>
<td>NCT01920698</td>
<td>Multicentre Randomized Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation (MITRA-FR)</td>
<td>288</td>
<td>Oct 2017</td>
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### NCT Numbers and Trial Names

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<tr>
<td>NCT02371512</td>
<td>A Multicenter, Randomized, Controlled Study to Assess Mitral vAlve reconsTrucTion for advancEd Insufficiency of Functional or ischEmic ORigiN (MATTERHORN)</td>
<td>210</td>
<td>Dec 2017</td>
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<tr>
<td>NCT02444338</td>
<td>A Clinical Evaluation of the Safety and Effectiveness of the MitraClip System in the Treatment of Clinically Significant Functional Mitral Regurgitation</td>
<td>380</td>
<td>Sep 2019</td>
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NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

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### Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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

#### 2015 Input

While this policy was under review in 2015, responses were solicited from physician specialty societies and academic medical centers. No input was received from physician specialty societies. However, input was received from 4 academic medical centers, one of which provided 4 responses, for a total of 7 responses. The input supported the use of transcatheter mitral valve repair in patients with degenerative mitral regurgitation at prohibitive risk of open surgery. The greatest consensus for selection criteria to determine “prohibitive risk” was for the use of the Society of Thoracic Surgeons predictive operative risk of 12% or higher, or a logistic EuroSCORE of 20% or higher.
Practice Guidelines and Position Statements

American College of Cardiology (ACC) and American Heart Association (AHA)

The American College of Cardiology (ACC) and American Heart Association released guidelines on the management of valvular heart disease in 2014.\(^{39}\) The guidelines included the following class IIB recommendation related to the use of transcatheter mitral valve repair (TMVR) for mitral regurgitation (MR):

Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal guideline-directed medical therapy for heart failure. (Level of Evidence: B.)

American College of Cardiology, American Association for Thoracic Surgery, et al.

The ACC, American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons released a position statement on transcatheter therapies for MR in 2014.\(^{40}\) This statement outlines critical components for successful transcatheter MR therapies and recommends ongoing research and inclusion of all patients treated with transcatheter MR therapies in a disease registry.

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

In 2012, the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery released joint guidelines on the management of valvular heart disease.\(^{41}\) These guidelines did not address TMVR.
Medicare National Coverage

In April 2015, The Centers for Medicare and Medicaid Services (CMS) issued a national coverage decision for the use of transcatheter mitral valve repair (TMVR).\(^{42}\)

CMS determined that it would cover TMVR under Coverage with Evidence Development (CED) for the treatment of significant symptomatic MR when performed according to an FDA-approved indication and when all of the following conditions are met:

1. The procedure is performed with a complete transcatheter MV repair system that has received FDA premarket approval (PMA) for that system’s FDA approved indication.

2. Both a cardiac surgeon experienced in MV surgery and a cardiologist experienced in MV disease have independently examined the patient face-to-face and evaluated the patient’s suitability for MV surgery and determination of prohibitive risk; and both physicians have documented the rationale for their clinical judgment and the rationale is available to the heart team.

3. The patient (pre-operatively and post-operatively) is under the care of a heart team made up of a cohesive, multi-disciplinary group of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. TMVR must be furnished in a hospital and with the appropriate infrastructure that includes but is not limited to:
   a. On-site active valvular heart disease surgical program with >2 hospital-based cardiothoracic surgeons experienced in valvular surgery;
   b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering catheterization laboratory-quality imaging,
   c. Non-invasive imaging expertise including transthoracic/transesophageal/3D echocardiography, vascular studies, and cardiac CT studies;
   d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications;
   e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures;
   f. Adequate outpatient clinical care facilities
   g. Appropriate volume requirements per the applicable qualifications below.
4. There are institutional and operator requirements for performing TMVR. The hospital must have the following:

   a. A surgical program that performs > 25 total mitral valve surgical procedures for severe MR per year of which at least 10 must be mitral valve repairs;

   b. An interventional cardiology program that performs > 1000 catheterizations per year, including > 400 percutaneous coronary interventions (PCIs) per year, with acceptable outcomes for conventional procedures compared to National Cardiovascular Data Registry (NCDR) benchmarks;

   c. The heart team must include:

       ▪ An interventional cardiologist(s) who:

           ○ Performs > 50 structural procedures per year including atrial septal defects (ASD), patent foramen ovale (PFO) and trans-septal punctures; AND

           ○ Must receive prior suitable training on the devices to be used; AND

           ○ Must be board-certified in interventional cardiology or board-certified/eligible in pediatric cardiology or similar boards from outside the United States

       ▪ Additional members of the heart team, including: cardiac echocardiographers, other cardiac imaging specialists, heart valve and heart failure specialists, electrophysiologists, cardiac anesthesiologists, intensivists, nurses, nurse practitioners, physician assistants, data/research coordinators, and a dedicated administrator;

   d. All cases must be submitted to a single national database;

   e. Ongoing continuing medical education (or the nursing/technologist equivalent) of 10 hours per year of relevant material;

   f. The cardiothoracic surgeon(s) must be board-certified in thoracic surgery or similar foreign equivalent.

5. The heart team's [sic] interventional cardiologist or a cardiothoracic surgeon must perform the TMVR. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

6. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TMVR patients; 2) accepts all manufactured devices; 3) follows the
patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56.

7. The registry should collect all data necessary and have a written executable plan. TMVR for MR uses that are not expressly listed as an FDA-approved indication when performed within a FDA-approved randomized clinical trial that fulfills all of the following:

a. TMVR must be performed by an interventional cardiologist or a cardiac surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

b. TMVR must be performed by an interventional cardiologist or a cardiac surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

- What is the patient’s post-TMVR quality of life (compared to pre-TMVR) at one year?
- What is the patient’s post-TMVR functional capacity (compared to pre-TMVR) at one year?

In addition, the clinical research study must address a series of questions at 1 year post procedure as outlined in the proposed decision memo.

**Regulatory Status**

In October 2013, the MitraClip® Clip Delivery System (Abbott Vascular, Menlo Park, CA) was approved by the U.S. Food and Drug Administration (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.”

FDA product code: NKM.

**References**


### History

<table>
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<th>Date</th>
<th>Comments</th>
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<tbody>
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<td>09/08/14</td>
<td>New Policy. Policy created with literature review through June 4, 2014. Transcatheter mitral valve repair considered investigational for all indications.</td>
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<tr>
<td>01/12/15</td>
<td>Coding update. New CPT codes 33418-33419, effective 1/1/15, added to policy; codes 0343T and 0344T deleted 12/31/14 noted on policy.</td>
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<tr>
<td>12/08/15</td>
<td>Annual Review. Added policy statement that Transcatheter mitral valve repair with the MitraClip is now medically necessary to treat degenerative mitral regurgitation when criteria are met. (Previously considered Investigational). Updated Policy Guidelines, with clarification about documented presence of risk score from one of the stated tools in the prohibitive risk definition. Added FDA indications for use. Policy updated with literature review through June 1, 2015; references added. Policy statement changed as noted. Codes 0343T and 0344T removed as deleted from codebook effective 12/31/14.</td>
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<td>02/01/16</td>
<td>Coding update. Added 93799.</td>
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<tr>
<td>10/21/16</td>
<td>Minor formatting edit. Restored reference hyperlinks.</td>
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  - Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

**Getting Help in Other Languages**

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

**Arabic (Arabic):**

يحيى هذا الإشعار معلومات هامة. قد يحيى هذا الإشعار معلومات مهمة بخصوص طالب أو طالبة. قد تكون هناك تأثيرات مهمة يتيح لك الحصول عليه من خلال هذه المعلومات. يتيح لك الحصول على هذه المعلومات مختلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357) للحصول على معلومات إضافية.

**Chinese (Chinese):**

本文有重要的信息。本通知可能有关於您透过 Premera Blue Cross 提交的申请或保险的重要讯息。本文可能有重要日期。您可能需要在截止日期之前采取行动。以保留您的健康保险或费用补贴。您有权利免费以您的母语得到本讯息和帮助。请拨电话 800-722-1471 (TTY: 800-842-5357).

**Creole (Ilocano):**


**Italian (Italian):**

본 통지에는 중요한 정보가 들어 있습니다. 즉 이 통지는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통해 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움 귀하의 안전과 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)에 전화해 주시오.