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## OVERVIEW

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 dilation 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 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 and for patients with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy.

## MEDICAL CRITERIA

### BlueCHiP for Medicare

See Coding section.

### Commercial Products

#### Primary Mitral Valve Regurgitation

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

Definition:

\* 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.

#### Heart Failure and Secondary Mitral Valve Regurgitation

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

Definitions:

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

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

\*Optimal medical therapy may be determined by guidelines from specialty societies such as:

- 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

## **PRIOR AUTHORIZATION**

### **BlueCHiP for Medicare**

See Coding section.

### **Commercial Products**

Prior authorization is recommended for Commercial Products.

## **POLICY STATEMENT**

### **BlueCHiP for Medicare**

Transcatheter mitral valve repair with a device approved by the U.S. Food and Drug Administration (FDA) may be considered medically necessary for patients enrolled in a Centers for Medicare and Medicaid Services (CMS) approved clinical trial. Refer to Related Policy section.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

### **Commercial Products**

Transcatheter mitral valve repair with a device approved by the U.S. Food and Drug Administration may be considered medically necessary when the medical criteria above has been met, and is not medically necessary in all other situations, as the evidence is insufficient to determine the effects of the technology on health outcomes.

## **COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable surgery benefits/coverage.

## **BACKGROUND**

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

Patients with MR generally fall into 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. In contrast, secondary MR results from left ventricular 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 left ventricular using medical therapy is the primary treatment strategy used in the United States.

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 left ventricular 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.

## **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 for the surgical management of MV, which are outlined as follows:

- MV surgery is recommended for the symptomatic patient with acute severe MR.
- MV surgery is beneficial for patients with chronic severe MR and New York Heart Association (NYHA) functional class II, III, or IV symptoms in the absence of severe LV dysfunction (severe LV dysfunction is defined as ejection fraction <0.30) and/or end-systolic dimension >55 mm.
- 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  $\geq$ 40 mm.
- 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.
- 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%.
- MV surgery is reasonable for asymptomatic patients with chronic severe MR, preserved LV function, and new onset of atrial fibrillation.
- MV surgery is reasonable for asymptomatic patients with chronic severe MR, preserved LV function, and pulmonary hypertension.
- 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.

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 United States, Goel et al (2014) found that 53% of patients did not have MV surgery performed, suggesting an unmet need for such patients.

Isolated MV surgery (repair or replacement) for severe chronic secondary MR is not generally recommended because there is no proven mortality reduction and an uncertain durable effect on symptoms.

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

### **Transcatheter MV Repair**

Transcatheter approaches have been investigated to address the unmet need for less invasive MV repair, particularly among inoperable patients who face prohibitively high surgical risks due to 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 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), has approval through the FDA premarket approval process for use in certain patients with symptomatic MR. 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. 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. 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 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) and the Monarc™ device (Edwards Lifesciences). The CE-marked Carillon Mitral Contour System is comprised of self-expanding proximal and distal anchors connected with a nitinol bridge, with the proximal end coronary sinus ostium and the distal anchor in the great cardiac vein. The size of the connection is controlled by manual pullback on the catheter (CE marked). The Carillon system was evaluated in the Carillon Mitral Annuloplasty Device European Union Study (AMADEUS) and the follow-up Tighten the Annulus Now (TITAN) 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 internal jugular vein and the other end 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.

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, which are cinched or connected to narrow the mitral annulus. Other transcatheter direct annuloplasty devices under investigation include the enCorTCTM device (MiCardia), which involves a percutaneously insertable annuloplasty ring that is adjustable using radiofrequency energy, a variation on its CE-marked enCorSQTM Mitral Valve Repair System, and the CardiobandTM Annuloplasty System (Valtech Cardio), an implantable annuloplasty band with a transfemoral venous delivery system.

### **Transcatheter MV Replacement**

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

### **Medical Management**

The standard treatment for patients with chronic secondary MR is medical management. Patients with chronic secondary MR should receive standard therapy for heart failure with reduced ejection fraction; standard management includes angiotensin converting enzyme inhibitor (or angiotensin II receptor blocker or angiotensin receptor-neprilysin inhibitor), b-blocker and mineralocorticoid receptor antagonist, and diuretic therapy as needed to treat volume overload.<sup>4,3</sup>Resynchronization therapy may provide symptomatic relief, improve LV function, and in some patients, lessen the severity of MR.

In October 2013, the MitraClip® Clip Delivery System (Abbott Vascular) was approved by the FDA through the premarket approval process for treatment of “significant symptomatic mitral regurgitation (MR ≥3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at a prohibitive risk for mitral valve surgery by a heart team.”

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

## **CODING**

### **BlueCHiP for Medicare**

The following codes may be allowed as part of a CMS approved clinical study:

**33418** Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis

**33419** Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

**0345T** Transcatheter mitral valve repair percutaneous approach via the coronary sinus

**Note:** If you are treating a BlueCHiP for Medicare member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials BlueCHiP for Medicare.

Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:

**Modifier Q0** – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare claims filed without the Q0 modifier will deny as not medically necessary)

**Modifier Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study

The following code requires prior authorization for BlueCHiP for Medicare and follows the medical necessity criteria found in the Medical Necessity policy:

**0544T** Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture (New Code Effective 7/1/2019)

### **Commercial Products**

The following codes are considered medically necessary when the medical criteria above has been met:

**33418** Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis

**33419** Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

**0345T** Transcatheter mitral valve repair percutaneous approach via the coronary sinus

**0544T** Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture (New Code Effective 7/1/2019)

## **RELATED POLICIES**

BlueCHiP for Medicare National and Local Coverage Determinations

Clinical Trials BlueCHiP for Medicare

Medical Necessity  
New Technology  
Prior Authorization via Web-Based Tool for Procedures

## **PUBLISHED**

Provider Update, December 2020  
Provider Update, April 2020  
Provider Update, September 2018  
Provider Update, July 2017  
Provider Update, May 2016

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