Transcatheter mitral valve (MV) repair is a potential alternative to surgical therapy for mitral regurgitation (MR). MR is a common valvular heart condition that can result from a primary structural abnormality of the MV complex or a dilated left ventricle due to ischemic or dilated cardiomyopathy, which leads to secondary dilatation of an anatomically normal MV.

FDA approval states the following: The MitraClip Clip Delivery System is indicated for the percutaneous reduction 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 open mitral valve surgery by a heart team, which 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.

II. Criteria/Guidelines
A. MitraClip Percutaneous Mitral Valve Repair System is covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:
   1. Patient has been diagnosed with significant symptomatic mitral regurgitation (MR ≥ 3+) due to abnormality of the mitral apparatus; and
   2. Patient must be determined to be at prohibitive risk for open mitral valve surgery as determined by at least two cardiovascular specialists, one of whom must be a cardiac surgeon experienced in mitral valve surgery. An independent face to face evaluation of the patient with a rationale for why the patient is at prohibitive risk of open mitral valve replacement surgery must be documented; and
   3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care; and
   4. The hospital must have the appropriate infrastructure that includes but is not limited to:
      a. On-site heart valve surgery program
b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped
   with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality
   imaging

c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed
   tomography (CT) and magnetic resonance (MR)

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

III. Limitations

A. The MitraClip Percutaneous Mitral Valve Repair System is not covered for patients in whom
   existing co-morbidities would preclude the expected benefit from correction of the mitral
   regurgitation.

B. MitraClip procedures will only be covered in hospital settings as described above.

C. The following conditions are not covered for percutaneous mitral valve repair because it is not
   known to be effective in improving health outcomes:
   1. Mitral valve regurgitation in patients who are not at prohibitive risk for open-heart surgery
   2. Patients with active inflammation of the heart (endocarditis), rheumatic mitral valve
      disease, blood clots present at the intended site of implant or blood clots in vessels
      through which access to the defect is gained
   3. Patients who cannot tolerate anti-platelet medications
   4. Patients with predominately functional mitral valve regurgitation
   5. All other indications

IV. Administrative Guidelines

A. Precertification is required. To precertify for procedure and place of treatment, please
   complete HMSA’s Precertification Request and mail or fax the form as indicated.
   1. Clinical notes including documentation of the severity of mitral valve dysfunction
   2. Documentation from at least two cardiac or cardiovascular specialists that the patient is at
      unacceptable risk for open surgical repair.

A. Precertification is not required for this service. Documentation supporting the medical necessity
   should be legible, maintained in the patient’s medical record and must be made available to HMSA
   upon request. HMSA reserves the right to perform retrospective review using the above criteria to
   validate if services rendered met payment determination criteria.

B. HMSA strongly encourages that each patient be enrolled in a formal registry that follows the
   patients for at least one calendar year and documents at a minimum the following items:
   Stroke, transient ischemic attacks, all-cause mortality, major vascular events, acute renal
   injury, repeat mitral valve procedures, quality of life.

C. Follow up with the above listed outcomes must be documented in the chart at normal post-
   surgical intervals for up to one year and made available for review by HMSA upon request.

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<th>CPT Codes</th>
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V. Scientific Background

Transcatheter mitral valve (MV) repair is a potential alternative to surgical therapy for mitral regurgitation (MR). MR is a common valvular heart condition that can result from a primary structural abnormality of the MV complex or a dilated left ventricle due to ischemic or dilated cardiomyopathy, which leads to secondary dilatation of an anatomically normal MV.

MR is the second most common valvular heart disease in people 75 years of age and older and accounts for 24% of all patients with valvular heart disease. 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. Degenerative disease (DMR) 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 disease (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 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.

The American College of Cardiology (ACC) and the American Heart Association (AHA) have issued joint guidelines for open surgical repair of the valves which stand as the standard of care, however elderly and or debilitated patients may not be candidates for the trauma of open repair. Transcatheter approaches allow procedures to be performed on the beating heart without the need for cardiopulmonary bypass. Percutaneous MV repair include direct leaflet repair; repair of the mitral annulus via direct annuloplasty or through indirect approaches 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.

One device for leaflet repair has been FDA-approved and has the largest body of evidence evaluating use. This is a percutaneously deployed device that approximates the open Alfieri edge-to-edge repair approach to treating MR. The transcatheter delivery system introduces a steerable sleeve and the device, which is a 4-mm wide clip fabricated from a cobalt-chromium alloy and polypropylene fabric. The clip is deployed via a transfemoral approach, with transseptal puncture used to access the left side of the heart and the MV. Placement of the clip leads to coapting of the mitral leaflets, thus creating a double-orifice valve.

The device received approval for treatment of “significant symptomatic mitral regurgitation of greater than or equal to 3+ due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at a prohibitive risk for mitral valve surgery by a heart team.”

“Prohibitive risk is defined by the presence of one or more of the following documented surgical risk factors: 1) STS predicted risk of 30-day mortality of greater than or equal to eight percent for mitral valve replacement; 2) porcelain aorta or extensively calcified ascending aorta; 3) frailty (assessed by two or more indices); 4) hostile chest; 5) sever liver disease/ cirrhosis (Model of End-stage Liver Disease (MELD) score of greater than 12); 6) severe pulmonary hypertension (systolic pulmonary artery pressure more than two-thirds systemic pressure); 7) unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, and internal mammary artery grafts at high risk of injury in a graft-dependent patient.”

FDA approval states the following: The MitraClip Clip Delivery System is indicated for the percutaneous reduction 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, which 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.

FDA approval was based on data from one randomized controlled trial and 2 patient registry databases. In the Endovascular Valve Edge-to-Edge Repair (EVEREST) II trial, patients with severe, symptomatic MR were randomized to endovascular repair with the MitraClip or to open surgical repair. Concurrent with the EVEREST II trial, study sponsors prospectively collected data from patients who were determined to be at prohibitively high surgical risk to be eligible for randomization but who underwent MitraClip placement, the EVEREST II High Risk Registry (HRR).

The Noridian local coverage determination for MitraClip Percutaneous Mitral Valve Repair System (A52662) provides coverage criteria and strongly encourages that each patient be enrolled in a formal registry that follows the patients for at least one calendar year and documents at a minimum the following items: Stroke, transient ischemic attacks, all-cause mortality, major vascular events, acute renal injury, repeat mitral valve procedures, quality of life.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA consider the application of this Medical Policy to the case at issue.

VII. References


7. Local Coverage Article: MitraClip Percutaneous Mitral Valve Repair System (A52661).