Percutaneous Mitral Valve Repair

I. 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.

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 (Society of Thoracic Surgeons score for MV repair >6% or MV replacement >8%) 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 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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<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<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>additional prosthesis(es) during same session (List separately in addition to code for primary procedure)</td>
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V. Scientific Background

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.

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 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.

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 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, 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.

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).