

Transcatheter Mitral Valve Repair (TMVR) Using the MitraClip Device

Policy Number: **M20150504026**
Effective Date: **7/1/2015**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☐ Child Health Plus ☒ Essential Plan
☐ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☐ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth medical necessity criteria for **transcatheter mitral valve repair (TMVR)** using the **MitraClip** device.

Policy:

Self-Funded:

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic **mitral regurgitation** (MR $\geq$ 3 to 4+) with the following criteria:

1. Primary abnormality of the mitral apparatus (**degenerative mitral regurgitation**); AND
2. Prohibitive risk, for mitral valve surgery determined by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease including documentation of the **STS Short-Term Risk Calculator** score (<https://www.sts.org/resources/risk-calculator>) ; AND
3. Severely symptomatic (New York Heart Association Class III or IV) heart failure despite medical therapy; AND
4. Existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

The MitraClip is contraindicated in patients with degenerative mitral regurgitation with the following conditions:

- 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, and in
- Patients who cannot tolerate blood thinners (anti-coagulation and anti-platelet medications).

Medicare Advantage:

There is currently a National Coverage Determination (NCD) for transcatheter mitral valve repair. Please refer to the links listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, and Essential Plan:

MediSource, MediSource Connect, and Essential Plan cover transcatheter mitral valve repair utilizing the Commercial criteria.

Background:

Traditionally, mitral valve repair surgery has been performed through a large central incision in the sternum that provides direct visualization of the heart, with cardiopulmonary bypass so that surgeons can operate on the arrested non-beating heart. To reduce morbidity, there has been a trend toward performing these types of mitral valve repairs and replacements using less invasive or minimally invasive techniques.

The MitraClip Mitral Valve Repair System is a minimally invasive method for mitral valve repair that does not require open heart surgery, cardiopulmonary bypass, or cardiac arrest. A multidisciplinary dedicated heart team approach (including primary [general] cardiologists, interventional cardiologists, cardiac surgeons, imaging specialists, valve and heart failure specialists, and cardiac anesthesiologists) is recommended for the evaluation and care of potential candidates for transcatheter mitral valve repair.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization not required. Criteria utilized upon retro-review.

Definitions

Degenerative mitral regurgitation is a primary abnormality of the mitral apparatus which is usually due to direct damage or wear of the MV leaflets, attached chords, or adjacent supporting tissues.

MitraClip is composed of a steerable guide catheter and a clip delivery system. The MitraClip is inserted via a steerable guide catheter through an incision in the groin into the femoral vein under fluoroscopic guidance. The catheter is guided through the femoral vein and is advanced into the right atrium of the heart. A guidewire is pushed out of the tip of the catheter, through the atrial septum, and into the left atrium to gain access to the mitral valve. A conical dilator is passed over the guidewire to create an opening in the septum that is large enough to enable entry of the MitraClip and into the left atrium, followed by insertion of the sheath of the catheter into the left atrium.

Mitral regurgitation is a common valvular disorder that can arise from abnormalities of any part of the mitral valve apparatus. These include the valve leaflets, annulus, chordae tendineae, and papillary muscles. Primary (also known as organic) causes of mitral regurgitation include degenerative mitral valve disease (including mitral valve prolapse), rheumatic heart disease, infective endocarditis, trauma, and congenital malformations. Secondary causes of mitral regurgitation include coronary heart disease, dilated cardiomyopathy, and hypertrophic cardiomyopathy.

STS Short-Term Risk Calculator calculates a patient's risk of mortality and morbidities for the most commonly performed cardiac surgeries, incorporating STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

Transcatheter mitral valve repair (TMVR) is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation (MR).

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Armstrong EJ, Foster, E. Transcatheter mitral valve repair. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed April 4, 2023.

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Hayes, Inc. Health Technology Assessment Percutaneous Mitral Valve Repair for Secondary (Functional) Mitral Valve Regurgitation in High-Risk Adults; Lansdale PA: December 2020.

O'Gara PT, Calhoun JH, Moon MR, et al. Transcatheter therapies for mitral regurgitation: a professional society overview from the American College of Cardiology, the American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions Foundation, and the Society of Thoracic Surgeons. J Am Coll Cardiol. 2014 Mar 4;63(8):840-52.

Otto, CM. Clinical manifestations and diagnosis of chronic mitral regurgitation. UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on June 11, 2024.

The Society of Thoracic Surgeons (STS) [web site]. STS Short-Term Risk Calculator. Available at: <https://www.sts.org/resources/risk-calculator>. Accessed July 1, 2025.

Writing Committee Members; Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2021 Feb 2;77(4):e25-e197

Writing committee, Bonow RO, O'Gara PT, Adams DH, et al. 2019 AATS/ACC/SCAI/STS expert consensus systems of care document: Operator and institutional recommendations and requirements for transcatheter mitral valve intervention: A joint report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and The Society of Thoracic Surgeons Endorsed by the Heart Failure Society of America. J Thorac Cardiovasc Surg. 2020 Jul;160(1):72-92.

Regulatory References

Centers for Medicaid and Medicare (CMS) [web site]. National Coverage Determination (NCD) Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (TMVR) (20.33). Available at: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=363&ncdver=3&keywordtype=starts&keyword=mitral+valve&bc=0> Accessed July 1, 2025.

New York State Department of Health [web site]. New York State Medicaid Program Physician Surgery Procedure Codes. April 2024 Available at: <https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf> Accessed July 1, 2025

United States Food and Drug Administration (FDA) [web site]. MitraClip Clip Delivery System – P100009. Last Updated:04/03/2023. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100009> Accessed July 1, 2025

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
11/1/2025	Health Care Services	Revised
11/1/2024	Health Care Services	Revised
8/1/2024	Health Care Services	Reviewed
8/1/2023	Health Care Services	Revised
6/1/2023	Health Care Services	Revised
6/1/2022	Health Care Services	Reviewed
6/1/2021	Health Care Services	Revised
7/1/2020	Health Care Services	Revised
6/1/2019	Medical Management	Revised
7/1/2018	Medical Management	Revised
8/1/2017	Medical Management	Revised
9/1/2016	Medical Management	Revised