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Medical Policy

Policy:	**202012**	**Effective Date:**	**10/01/2024**
SUBJECT:	**Transcatheter Mitral Valve Repair and Triscupid Valve Repair**	**Annual Review Date:**	**08/27/2024**
		Last Revised Date:	**08/27/2024**

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

Definition: Transcatheter mitral valve repair (TMVr) is a minimally invasive treatment for moderate-severe or severe symptomatic mitral regurgitation (MR). MR can be caused by degenerative disease of the valve leaflets (primary [degenerative] MR); or it can develop due to other causes (secondary [functional] MR), such as left ventricular abnormalities due to cardiomyopathy or coronary artery disease. Transcatheter tricuspid valve repair is a minimally invasive treatment for severe tricuspid regurgitation (TR). The goal for both approaches is to restore valve function without the need for open heart surgery. Currently, the following mitral or tricuspid valve repair devices have been approved by the US Food and Drug Administration (FDA) for treatment of:

- MR: the MitraClip Clip Delivery System and corresponding implantable device components (Abbott Medical, St. Paul, MN) and the PASCAL Precision Transcatheter Valve Repair System and corresponding implantable device components (Edwards LifeSciences, LLC, Irvine, CA).
- TR: TriClip G4 Transcatheter Edge-to-Edge Repair (TEER) System (Abbot Medical, St. Paul, MN).

The devices are implanted percutaneously, without the need for surgical access to the chest cavity or cardiopulmonary bypass. The devices work by grasping the mitral or tricuspid valve leaflets to help them remain fixed to one another throughout the cardiac cycle.

Medical Necessity:

I. Transcatheter mitral valve repair (TMVr) for Primary mitral regurgitation (MR): The Company considers TMVr using an FDA-approved device according to its approved indications (**CPT Codes 33418, 33419**) for primary (degenerative) MR (e.g., MitraClip Clip Delivery System or the PASCAL Precision Transcatheter Valve Repair System) **medically necessary** and eligible for reimbursement providing ***all*** of the following medical criteria are met:

a. Patient is aged 18 years or older; and
b. Patient has grade 3+ or higher symptomatic primary MR; and
c. Anatomy is favorable for the repair procedure; and
d. Patient is not a candidate for conventional open-heart mitral valve surgery†; and
e. Existing comorbidities would not preclude the expected benefits†; and
f. Patient has symptomatic New York Heart Association Class (NYHA) class III or IV heart failure.

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II. **TMVr for Secondary MR:** The Company considers TMVr using an FDA-approved device device according to its approved indications (**CPT Codes 33418, 33419**) for secondary (functional) MR (e.g., MitraClip NTR/XTR Clip Delivery System) **medically necessary** and eligible for reimbursement providing ***all*** of the following medical criteria are met:

a. Patient is aged 18 years or older; and
b. Patient has grade 3+ or higher symptomatic secondary MR (effective regurgitant orifice area [EROA] > 30 mm^2 and/or regurgitant volume > 45 mL); and
c. Left ventricular ejection fraction (LVEF) between 20% and 50%; and
d. Left ventricular end systolic diameter < 70 mm; and
e. Pulmonary arterial systolic pressure is less than or equal to 70 mmHg; and
f. Anatomy is favorable for the repair procedure; and
g. Patient has remained symptomatic despite the use of stable doses of maximally tolerated guideline-directed medical therapy (GDMT); and
h. Patient is not a candidate for conventional open-heart mitral valve surgery[†] or planned heart surgery for another condition; and
i. Existing comorbidities would not preclude the expected benefits[†]; and
j. Patient has symptomatic NYHA class II to IV heart failure.

NOTE: The Company considers the following **investigational** and **not** eligible for reimbursement:

- TMVr via coronary sinus approach (CPT Code 0345T).
- Transcatheter mitral valve replacement (CPT Codes 0483T, 0484T).
- Valve-in-valve replacement.
- Transcatheter mitral valve annuloplasty (CPT Code 0544T).
- Transseptal mitral chord repair (NeoChord).
- TMVr for:
  - Acute mitral regurgitation;
  - Hypertrophic cardiomyopathy;
  - Congenital heart disease with systemic right ventricle;
  - Re-intervention after failed repair;
  - Asymptomatic patients with primary mitral regurgitation.

[†]A cardiothoracic surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease **must** have independently examined the patient in-person and evaluated the patient's suitability for mitral valve surgery and determined the risk of an open surgical procedure; both providers have documented rationale for their clinical judgment, and rationale is available to the heart team. Patient (preoperatively and postoperatively) **must** be under the care of a heart team, a cohesive multidisciplinary team of medical professionals of appropriate training, education, and experience to provide guideline directed medical therapy of the member, including comprehensive advice on procedural risk, benefit, and alternatives to a proposed procedure.

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Grading of MR Severity

Severity	*Grade*	*Regurgitation fraction*
0	Trivial	< 5%
1+	Mild	5 to 15%
2+	Moderate	16 to 25%
3+	Moderate-severe	26 to 48%
4+	Severe	> 48%

Chew et al., 2018; Gelfand et al., 2006

NYHA Functional Classification

Class	*Symptoms*
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
IV	Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

American Heart Association, 2017

III. **Transcatheter tricuspid valve repair (CPT Codes 0545T, 0569T, 0570T, 0646T)** is considered **investigational** and **not** eligible for reimbursement.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the procedure performed regardless of how the procedure was coded by the Provider.

Approval or clearance by the U.S. Food and Drug Administration alone is not a basis for coverage.

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Coverage may differ for Medicare Advantage plan members; please see any applicable national and/or local coverage determinations for details. This information may be available at the Centers for Medicare & Medicaid Services (CMS) website.

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    - *Comparative Effectiveness Review of Percutaneous Mitral Valve Repair.* Dallas, TX: Hayes, Inc.; April 13, 2018. Annual Review: March 29, 2022.
    - *Evoque Tricuspid Valve Replacement System (Edwards Lifesciences Corp.) for Tricuspid Regurgitation.* Dallas, TX: Hayes, Inc.; February 8, 2024.
    - *Percutaneous Mitral Valve Repair for Secondary (Functional) Mitral Valve Regurgitation in High-Risk Adults*. Dallas, TX: Hayes, Inc.; Annual review: December 20, 2023.
    - *Transcatheter Mitral Valve Replacement for Mitral Regurgitation.* Dallas, TX: Hayes, Inc.; January 11, 2021. Annual Review: February 20, 2024.
    - *Transcatheter Tricuspid Valve Replacement for Tricuspid Valve Failure*. Dallas, TX: Hayes, Inc.; June 7, 2023.
    - *TriClip G4 System (Abbott Medical) Transcatheter Tricuspid Valve Repair for Tricuspid Regurgitation.* Dallas, TX: Hayes, Inc.; June 13, 2024.

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Applicable Code(s):	
CPT:	**33418, 33419, 0345T, 0483T, 0484T, 0545T, 0569T, 0570T, 0646T**
HCPCS:	
ICD10 Procedure Codes:	

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