02-33000-35

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Subject: Transcatheter Mitral Valve Repair/Replacement and Transcatheter Tricuspid Valve Repair

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Transcatheter mitral valve repair (TMVR) is an alternative to surgical therapy for mitral regurgitation (MR). Mitral regurgitation 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.

Mitral valve-in-valve replacement is a minimally invasive procedure designed to treat patients with failing surgical bioprosthetic mitral valves who are at high risk for complications with repeat open-heart surgery. The procedure involves deploying the replacement valve within the failing bioprosthetic valve using a catheter-based transapical or transseptal approach. Once in position, the replacement valve is expanded, pushing the leaflets of the failing bioprosthetic valve aside and taking over the valve function.

Tricuspid valve regurgitation, or tricuspid regurgitation, is a disorder in which the valve does not close properly. This causes blood to flow backward into the right upper heart chamber. Transcatheter tricuspid valve repair is being investigated for the treatment of tricuspid regurgitation. It is a minimally invasive procedure used to repair a malfunctioning tricuspid valve in patients who may not be candidates for traditional surgery due to comorbidities.

Several devices have received approval from the U.S. Food and Drug Administration (FDA) for the treatment of these conditions. For example, devices have been approved 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. Devices are also approved for patients with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy as well as for transcatheter mitral valve-in-valve replacement (TMViVR) in patients with a failing surgical bioprosthetic mitral valve who are at high or greater risk for repeat surgery.

POSITION STATEMENT:

Transcatheter mitral valve repair (TMVR) with a device **approved** by the FDA for use in mitral valve repair **meets the definition of medical necessity** for members with symptomatic, **primary** mitral regurgitation who are considered at risk for open surgery based on the presence of:

- Society for Thoracic Surgeons predicted mortality risk of 12% or greater; and/or
- Logistic EuroSCORE of 20% or greater.

Transcatheter mitral valve repair with a device approved by the FDA **meets the definition of medical necessity** for members with heart failure and moderate-to-severe or severe***** symptomatic secondary mitral regurgitation despite the use of maximally tolerated guideline-directed medical therapy.

*****[Moderate to severe or severe mitral regurgitation (MR) may be determined by: Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography or 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).]

Transcatheter mitral valve-in-valve replacement (TMViVR) with a device approved by the FDA **meets the definition of medical necessity** for members when all of the following conditions are present:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic mitral valve;
- New York Heart Association heart failure class II, III, or IV symptoms; **AND**
- One of the following (documented by 2 cardiovascular specialists, including a cardiac surgeon):
    - Member is not an operable candidate for open surgery; **OR**
    - Member is an operable candidate but is considered at increased surgical risk for open surgery******; **OR**
    - Member is considered at increased surgical risk for open surgery (eg, repeat sternotomy) due to a history of congenital vascular anomalies **OR**
    - Member has a complex intrathoracic surgical history.

[******FDA definition of high risk for open surgery: Society of Thoracic Surgeons (STS) predicted operative risk score of 8% or higher; or judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.]

Transcatheter mitral valve repair and transcatheter mitral valve-in-valve replacement is considered **experimental or investigational** in all other situations. The evidence is insufficient to determine the effects of the technology on health outcomes.

Transcatheter tricuspid valve repair or replacement is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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 **(Investigational)**
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture **(Investigational)**
0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis (**Investigational**)
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure) (**Investigational**)

ICD-10 Diagnosis Codes That Support Medical Necessity:

I01.1	Acute rheumatic endocarditis
I02.0	Rheumatic chorea with heart involvement
I05.1	Rheumatic mitral insufficiency
I05.2	Rheumatic mitral stenosis with insufficiency
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.1	Rheumatic disorders of both mitral and tricuspid valves
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves
I34.0-I34.9	Nonrheumatic mitral valve disorders

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Transcatheter Mitral Valve Repair (TMVR) (20.33) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Logistic EuroSCORE: European System for Cardiac Operative Risk Evaluation is a risk model which allows the calculation and predicts mortality according to the logistic regression equation. An online logistic EuroSCORE interactive calculator can be found at: http://www.euroscore.org/calc.html.

Society for Thoracic Surgeons (STS) Predicted Mortality Risk: a model that predicts the risk of operative mortality and morbidity after adult cardiac surgery on the basis of patient demographic, clinical variables and comparing outcomes across institutions with different patient populations. An online STS risk calculator can be found at: http://riskcalc.sts.org/stswebriskcalc/#/calculate.

RELATED GUIDELINES:

Transcatheter Aortic Valve Replacement, 02-33000-32

Transcatheter Pulmonary Valve Implantation, 02-33000-33

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 08/22/24.

GUIDELINE UPDATE INFORMATION:

09/15/16	New Medical Coverage Guideline.
07/15/17	Annual review; position statements maintained and references updated.
07/15/18	Annual review; description, position statement, and references updated.
07/01/19	Quarterly CPT/HCPCS update. Added code 0544T. Annual review; Position statements, coding, and references updated.
07/15/20	Annual review; Position statements maintained and references updated.
07/15/21	Annual review; Position statements maintained; references updated.
10/15/22	Review: Position statements maintained; coding and references updated.
05/25/23	Update to Program Exceptions section.
09/15/24	Review: Position statements, title, description, coding, and references updated.
10/15/24	Revision: Coding section updated.