

02-33000-35

Original Effective Date: 09/15/16

Reviewed: 09/22/22

Revised: 05/25/23

Subject: Transcatheter Mitral Valve Repair (TMVR)

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.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

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. 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 (primary MR) in patients considered at prohibitive risk for surgery and for patients with heart failure and moderate-to-severe or severe symptomatic secondary MR despite the use of maximally tolerated guideline-directed medical therapy.

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 repair is considered **experimental or investigational** in all other situations. 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)
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture (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:

[02-33000-33, Transcatheter Pulmonary Valve Implantation](#)

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 09/22/22.

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.