HEALTHHELP®

A WNS COMPANY

2025 Transcatheter Mitral Valve Repair (TMVR)

Cardiology

CARD-CTMV-HH

Last Review Date: 03/25/2025
Previous Review Date: 04/03/2024
Guideline Initiated: 06/30/2019

Table of Contents

Transcatheter Mitral Valve Repair (TMVR)

NCD 20.33
Coverage criteria for this NCD has administrative indications for consideration.
See also, **NCD 20.33** : Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.

Preamble: Pediatric Cardiology Preamble

HealthHelp's clinical guidelines for the Cardiology program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

TMVR Contraindications

Transcatheter mitral valve repair (TMVR) is contraindicated for **ANY** of the following:

1. Anticoagulation or anti-platelet medication is **NOT** tolerated.
   Reference: [6]
2. Active endocarditis or bacteremia is being treated.
   Reference: [8]
3. Life expectancy is less than 1 year.
   References: [6] [9] [2]
4. Mitral valve surgery history.
   Reference: [6]
5. Rheumatic mitral valve disease
   ***Reference*:** [8]
6. Thrombus (blood clot) is present (eg, intracardiac or femoral vein).
   Reference: [8]
7. Valve morphology is prohibitive, (eg, mitral clefts, perforation, severe calcifications, stenosis).
   References: [8] [6]

HEALTHHELP®

A WNS COMPANY

TMVR Guideline

Transcatheter mitral valve repair (TMVR)/transcatheter edge-to-edge repair (TEER) (eg, MitraClip™) is considered medically appropriate for the treatment of mitral valve regurgitation (MR) when the documentation demonstrates **ALL** of the following[1]

1. **NO** TMVR contraindications (*see above*)
2. Anatomy is appropriate for transcatheter approach.
   Reference: [2]
3. **ANY** of the following:
   a. Primary (degenerative) mitral regurgitation (MR) with **ALL** of the following:
      i. MR is severe, demonstrated with **ANY** of the following:
         A. Angiographic MR severity is grade 3+ to 4+.
         B. Echocardiography (ECHO) or Cardiac magnetic resonance (CMR) demonstrates with **ANY** of the following:
            I. Central jet MR is more than 40% left atrial or holosystolic eccentric jet MR.
            II. Effective regurgitant orifice (ERO) is 0.4 cm^2 or more.
            III. Regurgitant fraction is 50% or more.
            IV. Regurgitant volume is 60 mL or more.
            V. Vena contracta is 0.7 cm or more.
      ii. New York Heart Association (NYHA) class III or IV and severely symptomatic (eg. decreased exercise tolerance or exertional dyspnea)
      iii. Surgical risk for valve surgery determined by a heart team to be high or prohibitive with **ANY** of the following[2]
         A. Frailty indicated on 1 or more indices (moderate to severe)
         B. Mortality or major morbidity (all-cause) predictive risk is over 50% at 1 year.

[1]When intervention is considered for treatment of severe valvular heart disease, evaluation should be completed by a Multidisciplinary Heart Valve Team and mitral valve TEERs must be furnished in a hospital with appropriate infrastructure and experience. [6]

[2]Determination for suitability for mitral valve surgery and prohibitive risk should follow a face-to-face independent examination by both a cardiothoracic surgeon experienced in mitral valve surgery, and a cardiologist experienced in mitral valve disease, with the documented rationale available to the heart team. [9]

C. Organ system compromise, at least 1 organ system, is **NOT** expected to improve post-operatively.

D. Procedure-specific impediment (eg, chest malformation, radiation damage, severe calcification/porcelain ascending aorta, tracheotomy)

E. The Society of Thoracic Surgeons (STS)-predicted risk of mortality is over 8%. (STS Predicted Risk of Mortality: https://acsdriskcalc.research.sts.org/)

b. Secondary (functional) chronic MR with **ALL** of the following:

i. ECHO defined appropriate anatomy

ii. Left ventricular ejection fraction (LVEF) is between 20% and 50%.

iii. Left ventricular end-systolic diameter (LVESD) is 70 mm or less.

iv. MR is severe, demonstrated with **ANY** of the following:

A. Angiographic MR severity of grade 3+ to 4+

B. Cardiac MRI demonstrates severe MR indices.

C. ECHO with **ANY** of the following:

I. Central jet MR is more than 40% left atrial or holosystolic eccentric jet MR.

II. Effective regurgitant oriffance (ERO) is 0.4 cm^2 or more.

III. Regurgitant fraction is 50% or more.

IV. Regurgitant volume is 60 mL or more.

V. Vena contracta is 0.7 cm or more.

D. TEE indices demonstrates MR is severe.

v. NYHA class II, III, IV with persistent symptoms despite maximally tolerated guideline directed medical treatment (GDMT) for heart failure (ACE-I, beta blockers, aldosterone antagonist, and/or sacubitril/valsartan, and cardiac resynchronization therapy (CRT)/biventricular pacing, when indicated) and LVEF is less than 50%, LVEF between 20% and 50%, LVESD is 70mm or less and pulmonary artery systolic pressure is 70mmHg or less.

vi. Pulmonary artery systolic pressure (PASP) is 70 mm Hg or less.

c. Prosthetic valvular regurgitation, surgical risk is high or prohibitive and **ANY** of the following:

i. Hemolysis is intractable.

ii. Symptomatic and NYHA class is III or IV

References: [2] [6] [1] [9] [5] [3]

TMVR Procedure Codes

Table 1. Trans-catheter Mitral Valve Regurgitation Repair (TMVR) Associated Procedure Codes

CODE	DESCRIPTION
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

TMVR Summary of Changes

Transcatheter Mitral Valve Replacement (TMVR) clinical guideline from 2024 to 2025 had the following version changes:

- Citations updated per evidence.
- Evidence reviewed and indications remained the same.
- Added Pediatric Cardiac Preamble.

TMVR Definitions

Anticoagulation is a substance that is used to prevent and treat blood clots in blood vessels and the heart.

Cardiac Magnetic Resonance (CMR), also known as cardiac MRI, is a non-invasive medical imaging technology that uses magnetic resonance imaging (MRI) techniques to produce detailed images of the beating heart.

Echocardiography is a diagnostic test which uses ultrasound waves to make images of the heart chambers, valves and surrounding structures. It can measure cardiac output and is a sensitive test for fluid around the heart (pericardial effusion). It can also be used to detect abnormal anatomy or infections of the heart valves.

Ejection fraction (EF) is a measurement of how much blood the left ventricle pumps out with each contraction. It is measured in percentages with a normal measurement usually between 50 and 70%.

Endocarditis is inflammation of the inside lining of the heart chambers and heart valves (endocardium). It is caused by a bacterial or rarely, a fungal infection.

Clinical Frailty Scale:

- Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
- Well– People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, eg, seasonally.
- Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking
- Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up" and/or being tired during the day.
- Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.
- Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs, need help with bathing and might need minimal assistance (cuing, standby) with dressing.
- Severely Frail – Completely dependent for personal care from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).
- Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

Guideline-directed medical therapy (GDMT) refers to the optimal course of treatment for each stage of a chronic cardiac condition (eg, angina, heart failure), including those at high risk of disease progression but without structural heart disease or symptoms. The goal is titration of medications to maximum tolerated doses.

Left ventricular ejection fraction (LVEF), also known as ejection fraction (EF), measures the amount of blood the left ventricle of the heart pumps out to the body with each heartbeat.

Left ventricular end-diastolic diameter (LVEDD) is a common and important indicator in echocardiogram, which reflects the size of cardiac as well as left ventricular function. It is associated with progressive left ventricular insufficiency. At the same time, dilated LVEDD is linked to a high risk for heart failure and cardiovascular outcomes.

Left ventricular end-systolic dimension (LVESD) is a measurement of the left ventricle's size at the end of a heartbeat. It's a key indicator of how well the heart's left ventricle is functioning.

Mitral regurgitation (MR) is a common type of valvular heart disease that can result from a primary structural abnormality of the mitral valve (MV), or a secondary dilatation of an anatomically normal MV due to a dilated left ventricle caused by ischemic or dilated cardiomyopathy.

Table 1. Chronic Primary Mitral Regurgitation (MR) Stages [a.]

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Symptoms
A	At Risk	• Mild mitral valve prolapse with normal coaptation • Mild valve thickening and leaflet restriction	• NO MR jet or central jet area of less than 20% LA on Doppler • Vena contracta is less than 0.3 cm	• None
B	Progressive	• Moderate to severe mitral valve prolapse with normal coaptation • Rheumatic valve changes with leaflet restriction and loss of central coaptation • Prior IE	• Central jet MR is 20% to 40% LA or late systolic eccentric jet MR • Vena contracta is less than 0.7 cm • Reguritant volume is less than 60 mL • Reguritant fraction is less than 50% • ERO is less than 0.40 cm^2 • Angiographic grade 1+ to 2+	• None
C	Asymptomatic, Severe	• Severe mitral valve prolapse with loss of coaptation or flail leaflet • Rheumatic valve changes with leaflet restriction and loss of central coaptation • Prior IE • Thickening of leaflets with radiation heart disease	• Central jet MR is more than 40% LA or holosystolic eccentric jet MR • Vena contracta 0.7 cm or more • Reguritant volume 60 mL or more • Regurgitant fraction 50 % or more • ERO 0.40 cm^2 or more • Angiographic grade 3+ to 4+	• None

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Symptoms
D	Symptomatic, Severe	• Severe mitral valve prolapse with loss of coaptation or flail leaflet • Rheumatic valve changes with leaflet restriction and loss of central coaptation • Prior IE • Thickening of leaflets with radiation heart disease	• Central jet mitral regurgitation is more than 40% LA or holosystolic eccentric jet MR • Vena contracta 0.7 cm or more • Reguritant volume 60 mL or more • Regurgitant fraction 50 % or more • ERO 0.40 cm^2 or more • Angiographic grade 3+ to 4+	• Exercise tolerance decreased • Dyspnea on exertion

[a.]Otto C, Nishimura R, Bonow R, 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. Circulation 143(5), pp. e72-e227; December 17, 2020.

Mitral Regurgitation Index or Indices is a semiquantitative measurement of the severity of mitral regurgitation (MR). It's calculated using six echocardiographic variables which includes: Jet Penetration, PISA (Proximal Isovelocity Surface Area), CW (Continuous-wave) Jet Intensity and Character, Pulmonary Artery Pressure (PAP), Pulmonary Venous Flow Pattern, and Left Atrial Size.

Mitral valve is a heart valve that regulates blood flow between the left atrium and left ventricle. The mitral valve is also known as the bicuspid valve or the left atrioventricular valve.

Mitral valve cleft (MVC) is a complete or incomplete cleft in part of the mitral valve due to congenital mitral hypoplasia. This condition may be present with or without other congenital heart defects.

Mitral valve stenosis is a narrowing of the valve between the two left heart chambers. The narrowed valve reduces or blocks blood flow into the heart's main pumping chamber.

Table 2. New York Heart Association (NYHA) Functional Classification for Heart Failure

CLASS	SYMPTOMS EXPERIENCED
Class I (Mild)	Cardiac disease, but no symptoms and no limitation in ordinary physical activity (eg, shortness of breath when walking, climbing stairs).
Class II (Mild)	Mild symptoms (eg, mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III (Moderate)	Marked limitation in activity due to symptoms, even during less-than-ordinary activity, (eg, walking short distances [20–100 m]). Comfortable only at rest. Class IIIa: no dyspnea at rest. Class IIIb: recent dyspnea at rest.
Class IV (Severe)	Severe limitations. Experience symptoms while at rest. Unable to carry on any physical activity without discomfort.

Pulmonary artery systolic pressure (PASP) refers to the pressure in the pulmonary arteries during the contraction phase of the heart, essentially measuring the force at which blood is pushed through the pulmonary arteries to the lungs; it is a key indicator for assessing the health

of the pulmonary circulation, and elevated PASP can suggest pulmonary hypertension, a condition where blood pressure in the lungs is abnormally high.

Regurgitant fraction is referred to as the backflowing blood volume divided by the forward flow volume and is expressed in percent.

Regurgitant jet is a term used to describe the jet of blood seen back-flowing through a valve on an echo when mitral regurgitation is present. The jet is described as central or eccentric depending on the location.

Regurgitant volume refers to the volume of blood flowing backwards or in the reverse direction through the valvular plane within a beat or cardiac cycle.

Rheumatic mitral valve disease is a type of heart disease that occurs when the mitral valve is damaged by rheumatic fever. Rheumatic fever is an inflammatory condition that can affect the heart, joints, brain, and skin.

Society of Thoracic Surgeons (STS) score is a screening tool used for patients being considered for cardiac surgery. The tool incorporates STS risk models and is designed to account for the impact of patient risk factors on operative mortality and morbidity.

The Society for Thoracic Surgeons (STS), "Risk-Calculator." [Online]: Available: https://acsdriskcalc.research.sts.org/

Thrombus is a blood clot that forms on the wall of a blood vessel or in the heart when blood platelets, proteins and cells stick together. A thrombus may block the flow of blood.

Transcatheter mitral valve repair (TMVR), also known as transcatheter edge-to-edge repair (TEER) is used in the treatment of mitral regurgitation (MR). A TEER device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation (MR).

Transesophageal echocardiography (TEE) uses high-frequency sound waves (ultrasound) to make detailed pictures of the heart and the blood vessels that lead to and from it. Unlike a standard echocardiogram, the echo transducer that produces the sound waves for TEE is attached to a thin tube that passes through the mouth and throat, and into the esophagus. The esophagus is close to the upper chambers of the heart and clear images of the heart structures and valves can be obtained.

Valve morphology refers to the structure of a heart valve, and abnormal valve morphology is any structural abnormality in a cardiac valve. The morphology of a valve can be classified in a number of ways, including:

Tricuspid: A type of valve morphology

Bicuspid: Also known as the mitral valve, this type of valve allows blood to flow from the left atrium to the left ventricle

Asymmetric: A type of bicuspid aortic valve (BAV) morphology with two cusp angles of 240°–120°

Symmetric: A type of BAV morphology with two cusp angles of 180°–180°

Valvular heart disease is a condition when any valve in the heart has damage or is diseased. When heart valves are diseased, the heart cannot effectively pump blood throughout the body and

has to work harder to pump, either while the blood is leaking back into the chamber or against a narrowed opening. This can lead to heart failure, sudden cardiac arrest and death.

Vena contracta is the narrowest part of the jet, just distal to the regurgitant orifice. Vena contracta dimensions reflect the severity of regurgitation.

TMVR References

[1] Bonow, R.O., O'Gara, P.T., . . . Woo, Y.J. (2020). 2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee. *Journal of the American College of Cardiology, 75*(17), 2236-2270.

[2] Hahn, R.T. & Bonow, R.O. (2022). Mitral Regurgitation. P. Libby & R.O. Bonow (Eds.). *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine* (12), (pp. 1455-1472). Philadelphia: Elsevier.

[3] Lindenfeld, J. & Zile, M.R. (2022). Devices for Monitoring and Managing Heart Failure. P. Libby & R.O. Bonow (Eds.). *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine* (12), (pp. 1107-1118). Philadelphia, PA: Elsevier.

[4] Nishimura, R.A., Otto, C.M., . . . Thompson, A. (2017). 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation, 135*(25), e1159-e1195.

[5] O'Gara, P.T. & Mack, M.J. (2020). Secondary Mitral Regurgitation. *American College of Cardiology*. Retrieved: January 2025. https://www.acc.org/latest-in-cardiology/ten-points-to-remember/2020/10/08/19/16/secondary-mitral-regurgitation

[6] Otto, C.M., Nishimura, R.A., . . . Toly, C. (2021). 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. *Journal of the American College of Cardiology, 77*(4), 450–500.

[7] Rosengart, T.K., Aberle, C.M. & Ryan, C. (2022). Acquired Heart Disease: Valvular. C.M. Townsend, R.D. Beauchamp, . . . Mattox, K.L. (Eds.). *Sabiston Textbook of Surgery* (21). (pp. 1711-1742). Philadelphia: Elsevier.

[8] Salcedo, E.E., Quaife, R.A. & Carroll, J.D. (2022). Transcatheter Mitral Valve Repair. C.M. Otto (Ed.). *Practice of Clinical Echocardiography* (6). (pp. 567-587). Philadelphia, PA: Elsevier.

[9] Vahanian, A., Beyersdolf, F., . . . Wojakowski, W. (2022). 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *European Heart Journal, 43*(7), 561-632.

[10] Zoghbi, W.A., Adams, D., . . . Weissman, N.J. (2017). Recommendations for Noninvasive Evaluation of Native Valvular Regurgitation: A Report from the American Society of

Echocardiography Developed in Collaboration with the Society for Cardiovascular Magnetic Resonance. *Journal of the American Society of Echocardiography, 30*(4), 303-371.

Disclaimer section

Purpose

The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.

Clinician Review

These clinical guidelines neither preempt clinical judgment of trained professionals nor advise anyone on how to practice medicine. Healthcare professionals using these clinical guidelines are responsible for all clinical decisions based on their assessment. All Clinical Reviewers are instructed to apply clinical indications based on individual patient assessment and documentation, within the scope of their clinical license.

Payment

The use of these clinical guidelines does not provide authorization, certification, explanation of benefits, or guarantee of payment; nor do the guidelines substitute for, or constitute, medical advice. Federal and State law, as well as member benefit contract language (including definitions and specific contract provisions/exclusions) take precedence over clinical guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and payment are the responsibility of the health plan. Nothing contained within this document can be interpreted to mean otherwise.

Registered Trademarks (®/™) and Copyright (©)

All trademarks, product names, logos, and brand names are the property of their respective owners and are used for purposes of information and/or illustration only. Current Procedural Terminology (CPT)®™ is a registered trademark of the American Medical Association (AMA). No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any

form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from HealthHelp.

National and Local Coverage Determination (NCD and LCD)

NOTICE
To ensure appropriate review occurs to the most current NCD and/or LCD, always defer to https://www.cms.gov/medicare-coverage-database/search.aspx.

Background

National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) are payment policy documents outlined by the Centers for Medicare and Medicaid Services (CMS) and the government's delegated Medicare Audit Contractors (MACs) that operate regionally in jurisdictions.
CMS introduced variation between different jurisdictions/Medicare Audit Contractors (MACs) and their associated covered code lists with the transition to ICD 10. The variation resulted in jurisdictions independently defining how codes are applied for exclusions, limitations, groupings, ranges, etc. for the medical necessity indications outlined in the NCD and LCD. Due to this variation, there is an inconsistent use/application of codes and coverage determinations across the United States between the different MACs.
In addition, **WITHOUT** notice, CMS can change the codes that indicate medical necessity and the format of the coverage determinations/associated documents (eg, Articles). This is an additional challenge for organizations to keep up with ongoing, unplanned changes in covered codes and medical necessity indications.

Medical Necessity Codes

Due to the variation in code application between jurisdictions/MACs and that updates can happen without notification, HealthHelp is not able to guarantee full accuracy of the codes listed for any Coverage Determination, and advises that prior to use, the associated Coverage Determination Articles are reviewed to ensure applicability to HealthHelp's programs and any associated NCDs and LCDs.

For Internal Use Only:

11248 11249 11253 11282 11325 11328 11333 11349 11350 11351 11352 11354 11355 11356 11358 11359 11360 11361 11362 11365 11366 11367 11368 11369 11370 11374 11375 11394 11395 11396 11565