Cardio Policy:

Trans Catheter Edge to Edge Repair (TEER) of Mitral Valve

POLICY NUMBER UM CARDIO_1296	**SUBJECT** Trans Catheter Edge to Edge Repair (TEER) of Mitral Valve	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 6**
DATES COMMITTEE REVIEWED 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 02/01/23, 03/08/23, 12/20/23	**APPROVAL DATE** December 20, 2023	**EFFECTIVE DATE** December 22, 2023	**COMMITTEE APPROVAL DATES** 05/24/16, 12/21/16, 10/11/17, 11/14/18, 03/13/19, 05/08/19, 08/14/19, 12/11/19, 08/12/20, 08/11/21, 09/14/22, 02/01/23, 03/08/23, 12/20/2023
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for Trans Catheter Edge to Edge Repair (TEER or MITRACLIP) of Mitral Valve.

II. DEFINITIONS

Mitral regurgitation (MR) is the most common type of heart valve insufficiency in the United States. Patients with MR are at risk of poor quality of life, marked limitation in activity, repeated heart failure hospitalizations, and increased mortality. Mitral valve comprises of two valve leaflets and is attached to papillary muscles which prevents the leaflets from prolapsing back into the left atrium. MR is the backward flow of blood during left ventricular (LV) systole, which over time may lead to progressive symptoms and structural changes to the heart, including progressive ventricular dilation and worsening left ventricular function. Primary (degenerative) MR results from structural failure of the mitral valve; secondary (functional) MR results from left ventricular (LV) dysfunction with a largely preserved mitral valve. The underlying left ventricular dysfunction may be caused by coronary artery disease or numerous other causes.

In assessing patient with chronic severe symptomatic MR, it is critical to distinguish between chronic primary (degenerative) MR and chronic secondary (functional) MR, as these 2 conditions have more differences than similarities. These patients are clinically categorized as Stage D Chronic Primary MR or Stage D Chronic Secondary MR.

Stage D	Etiology	Symptoms	Valve Anatomy and associated	Hemodynamics

			Cardiac findings	
Primary MR	Degenerative-Severe Prolapse/Flail leaflets/Rheumatic/Prior IE/Thickening of leaflets due to Radiation	-Decreased exercise tolerance -Exertional dyspnea	-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 >40% LA or holosystolic eccentric jet MR -ERO ≥0.40 cm^2 -Vena contracta ≥0.7 cm -Regurgitant volume ≥60mL -Regurgitant fraction ≥50% -Angiographic grade 3-4+ -Pulmonary HTN -Mod or Severe LA enlargement
Secondary MR	-Ischemic Cardiomyopathy (MI), LVEF 20-50% -Non-Ischemic Cardiomyopathy, LVEF 20-50%	-HF symptoms due to MR even after revascularization and optimization of medical therapy -Decreased exercise tolerance -Exertional dyspnea	-Regional wall motion abnormalities and/or LV dilation with severe tethering of mitral leaflet -Annular dilation with severe loss of central coaptation of the mitral leaflets	-ERO ≥0.40cm^2 -Regurgitant volume ≥60mL -Regurgitant fraction ≥50%

The need for treatment usually depends on the condition and function of the heart. The standard treatment for individuals with severe and symptomatic MR has been surgical treatment - repair or replacement of the mitral valve based on well-defined treatment guidelines. However, patients with severe Primary MR due to leaflet etiology, advanced age, LV dysfunction (EF less than 30%) and comorbidities were deemed as prohibitive risk surgical candidates (STS risk score of surgical mortality greater than 50% at one year) and therefore conventional open mitral valve repair or replacement was often not presented as an option for these individuals. TEER which is a

percutaneous mitral leaflet clipping procedure has shown improved outcomes in this patient population. TEER involves clipping together a portion of the mitral valve leaflets as a treatment for reducing severe Primary MR with the intended outcomes to improve recovery of the heart from overwork, improve function and potentially halt the progression of heart failure. The procedure is performed under general anesthesia via echocardiographic and fluoroscopic guidance.

Society of Thoracic Surgeons (STS) Score: It is used to calculate a patient's risk of mortality and other morbidities, such as long length of stay, risk of stroke, risk of prolonged ventilation, infection, and renal failure etc. The STS score risk calculator incorporates the 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.

Risk Assessment Combining STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments.

	Low Risk (Must Meet ALL Criteria in This Column)	Intermediate Risk (Any 1 Criterion in This Column)	High Risk (Any 1 Criterion in This Column)	Prohibitive Risk (Any 1 Criterion in This Column)
STS PROM*	<4% AND	4% to 8% OR	>8% OR	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y OR
Frailty†	None AND	1 Index (mild) OR	≥2 Indices (moderate to severe) OR	
Major organ system compromise not to be improved postoperatively	None AND	1 Organ system OR	No more than 2 organ systems OR	≥3 Organ systems OR
Procedure- specific impediment§	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

*Use of the STS PROM (Predictive Risk of Mortality) is to predict risk in a given institution with reasonable reliability is appropriate only if institutional outcomes are within 1 standard deviation of STS average observed/expected ratio for the procedure in question.

†Seven frailty indices: Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting, and urinary continence) and independence in ambulation (no walking aid or assist required or 5 meter walk in less than 6 s). Other scoring systems can be applied to calculate no, mild-, or moderate-to-severe frailty.

‡Examples of major organ system compromise: Cardiac-severe LV systolic or diastolic dysfunction or RV dysfunction, fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 less than 50% or DLCO2 less than 50% of predicted; CNS dysfunction (dementia, Alzheimer's disease, Parkinson's disease, CVA with persistent physical limitation); GI dysfunction-Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin less than 3.0; cancer-active

malignancy; and liver-any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.

§Examples: tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost–effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care – Median Score 7-9

Maybe Appropriate Care – Median Score 4-6

Rarely Appropriate Care – Median Score 1-3

Guideline directed medical therapy (GDMT) are outlined by joint American College of Cardiology (ACC)/American Heart Association (AHA) in cardiovascular clinical practice guidelines as Class I recommendation. These are maximally tolerated medications for a cardiovascular condition, when prescribed, have shown to improve healthcare outcomes such as survival along with significant reduction in major adverse cardiovascular events and hospitalization. For all recommended drug treatment regimens, the prescriber should confirm the dosage with product insert material and carefully evaluate for contraindications and interactions[2,3,5,6,7,8]

III. POLICY

Patients should be on maximally tolerated GDMT.

Indications for approving for medical necessity are as follows:

A. TEER may be considered for severely symptomatic patients (NYHA Class III to IV) with chronic severe primary or degenerative MR (Stage D) who have favorable anatomy for the procedure with a reasonable life expectancy (greater than1 year) on optimal Guideline Directed Medical Therapy for Heart Failure and have an STS high or prohibitive surgical risk of death or major morbidity greater than 50% at one year. **(AUC Score 6)**[1,2,4, 5, 6, 7, 8, 9]

B. TEER may be considered for severely symptomatic patients (NYHA Class III to IV) with chronic moderately severe or severe secondary or functional MR (Stage D) who have favorable anatomy for the procedure with a reasonable life expectancy (greater than1 year) on optimal Guideline Directed Medical Therapy for Heart Failure and have a STS high or prohibited surgical risk of death or major morbidity greater than 8% or greater than 50% respectively, at one year or Frailty index of greater than or equal to 2 or a possibility of no more than 2 major organ systems compromise not to be improved. **(AUC Score 5)**[1,2,3,4, 5, 6, 7, 8, 9]

Limitations:

Following are the exclusion criteria for TEER-

A. Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen

B. Life expectancy less than 12 months

C. Active endocarditis of the mitral valve

D. Rheumatic mitral valve disease with Mitral stenosis Mean Mitral gradient greater than 5 mm Hg or MV area less than 4.0 cm^2

E. Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

F. Leaflet pathology involves commissural segments, perforation, or clefts

G. Severe leaflet/annular calcification in grasping area

H. Grasping zone length less than 7mm

I. Presence of coexisting aortic or tricuspid valve disease requiring surgery or transcatheter intervention; or COPD requiring continuous home oxygen therapy or chronic outpatient oral steroid use; or

J. ACC/AHA stage D heart failure; or

K. Estimated pulmonary artery systolic pressure (PASP) greater than 70 mmHg as assessed by echocardiography or right heart catheterization, unless active vasodilator therapy in the catheterization laboratory is able to reduce the pulmonary vascular resistance (PVR) to less than 3 Wood Units or between 3 and 4.5 Wood Units with a v wave less than twice the mean of the pulmonary capillary wedge pressure (PCWP); or

L. Hemodynamic instability requiring inotropic support or mechanical heart assistance; or

M. Physical evidence of right-sided congestive heart failure with echocardiographic evidence of moderate or severe right ventricular dysfunction; or

N. Need for emergent or urgent surgery for any reason or any planned cardiac surgery within the next 12 months

O. In addition to #1-14, use of TEER (Mitra Clip Device) is not recommended for Primary (degenerative) MR if
   1. Flail width greater than 15 mm and flail gap greater than 10 mm
   2. Multi-segment pathology; highly mobile flail leaflet with multiple ruptured chords
   3. LV End Systolic Dimension greater than 55 mm

P. In addition to #1-14, use of TEER (Mitra Clip Device) is not recommended for Secondary (Functional) MR
   1. LV End Systolic Dimension greater than 70mm

Q. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

R. Prior to performing TEER in a patient with chronic severe MR the following must be considered: Predicted or observed lack of response to maximally tolerated to GDMT[2,3, 5,6,7,8]

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review:
   1. Cardiologist/Interventional Cardiologist and Cardiothoracic surgeon progress notes that prompted request that would support that patient is not a candidate for mitral valve surgery
   2. Most recent ECHO, TEE, Cardiac Cath report
   3. STS surgical risk score report

B. Primary codes appropriate for this service: 33418, 33419 (additional prosthesis during same session)

C. Place/Site of Service: Inpatient hospital (21)

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

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