

Evolut Clinical Guideline 7310 for Mitral Valve Surgery

<u>Guideline Number:</u> <u>Evolut CG 7310</u>	<u>Applicable Codes</u>	
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TABLE OF CONTENTS

STATEMENT	22
GENERAL INFORMATION	22
PURPOSE	22
CLINICAL REASONING	22
INDICATIONS FOR MITRAL VALVE REPAIR OR REPLACEMENT	22
MITRAL REGURGITATION (MR)	32
Primary MR	32
Secondary MR	33
MITRAL STENOSIS (MS)	33
Rheumatic MS	43
Non-rheumatic (calcific)	44
CODING AND STANDARDS	44
CODES	44
APPLICABLE LINES OF BUSINESS	44
BACKGROUND	44
CALCIFIC MITRAL STENOSIS	44
AUC SCORE	54
ACRONYMS/ABBREVIATIONS	55
SUMMARY OF EVIDENCE	55
ANALYSIS OF EVIDENCE	87
POLICY HISTORY	88
LEGAL AND COMPLIANCE	98
GUIDELINE APPROVAL	98
Committee	98
DISCLAIMER	98
REFERENCES	1010

STATEMENT

General Information

- **It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.**
- **Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.**
- **The guideline criteria in the following sections were developed utilizing evidence-based and peer-reviewed resources from medical publications and societal organization guidelines as well as from widely accepted standard of care, best practice recommendations.**

Purpose

Indications for determining medical necessity for Mitral Valve Surgery, which includes open-procedure repair or replacement of a mitral valve.

Clinical Reasoning

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This guideline first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for decision-making and underscores our commitment to upholding the highest standards of care. (1-5)

INDICATIONS FOR MITRAL VALVE REPAIR OR REPLACEMENT

Mitral Regurgitation (MR)

Primary MR

- **Acute severe MR** ⁽⁶⁾
- **Symptomatic chronic severe MR (regardless of left ventricular (LV) systolic function)** ⁽⁶⁾
- **Asymptomatic Patients** ⁽⁶⁻⁸⁾
 - **Severe MR with LV dysfunction (LV ejection fraction (LVEF) ≤ 60% and/or LV end-systolic dimension (LVESD) ≥ 40 mm)**
 - **Severe MR with preserved LV function (LVEF >60%, LVESD <40 mm) and**
 - **Atrial fibrillation (AF) secondary to MR or**
 - **Pulmonary hypertension (systolic pulmonary artery pressure (SPAP) at rest >50 mmHg)**
 - **Surgical MV repair can be considered in severe MR with preserved LV function (LVEF >60%, LVESD <40 mm) and**
 - **> 95% likelihood of successful and durable repair without residual regurgitation and**
 - **Mortality < 1%**
 - **Severe MR with preserved LV function (LVEF >60 %, LVESD <40%) but with progressive increase in LV size or decrease in LVEF on at least 3 serial imaging studies, irrespective of likelihood of successful repair.**

Secondary MR ^(6,7)

Chronic secondary mitral regurgitation typically develops because of LV systolic dysfunction. Therefore, Guideline Directed Medical Therapy (GDMT) for heart failure, including standard medication (and, as indicated, coronary revascularization and biventricular pacing) should be the foundation of treatment. Surgical or transcatheter therapies should only be contemplated in those patients who are genuinely refractory to full GDMT.

- **Chronic severe MR with LV systolic dysfunction (LVEF < 50%) with persistent severe symptoms (New York Heart Association (NYHA) class III or IV) despite GDMT for HF**
- **Chronic severe MR in patients undergoing another cardiac surgery such as coronary artery bypass graft (CABG)**
- **Chronic severe MR from annular dilatation with preserved LVEF (>= 50%) with persistent severe symptoms (NYHA class III or IV) despite therapy for heart failure (HF) and therapy for AF or other comorbidities**

Mitral Stenosis (MS)

Rheumatic MS (6,7)

- **Severely symptomatic (NYHA class III or IV) severe MS with any of the following:**
 - **not a candidate for Percutaneous Mitral Balloon Commissurotomy (PMBC)**
 - **failed previous PMBC**
 - **no access to PMBC**
 - **undergoing another cardiac surgery**

Non-rheumatic (calcific) MS (6)

- **Intervention for severe calcific MS may be considered in severely symptomatic patients (NYHA class III or IV) only after shared decision making regarding high procedural risk (see Background section).**

CODING AND STANDARDS

Codes

33422, 33425, 33426, 33427, 33430, 33530

Applicable Lines of Business

<input checked="" type="checkbox"/>	<u>CHIP (Children’s Health Insurance Program)</u>
<input checked="" type="checkbox"/>	<u>Commercial</u>
<input checked="" type="checkbox"/>	<u>Exchange/Marketplace</u>
<input checked="" type="checkbox"/>	<u>Medicaid</u>
<input checked="" type="checkbox"/>	<u>Medicare Advantage</u>

BACKGROUND

Calcific Mitral Stenosis

Calcific (or degenerative) MS is a distinct condition that differs from rheumatic mitral stenosis. It results from calcification of the mitral annulus extending into the leaflet bases, causing narrowing of the annulus and rigidity of the leaflets. These patients are usually elderly and may have co-morbidities, including disease of other valves, making surgical intervention high-risk. Intervention for severe mitral annular calcification also

presents technical challenges due to the difficulty in securely attaching the prosthetic valve, and the valve may further narrow the orifice. Therefore, intervention should be delayed until symptoms are severely limiting and are refractory to aggressive medical therapy.

AUC Score

A reasonable diagnostic or therapeutic procedure care can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. ⁽²⁾

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

Acronyms/Abbreviations

AF: Atrial fibrillation

CABG: Coronary artery bypass graft

EF: Ejection fraction

GDMT: Guideline-directed medical therapy

HF: Heart failure

LV: Left ventricle

LVEF: Left ventricular ejection fraction

LVESD: Left ventricular end-systolic dimension

MR: Mitral regurgitation

MS: Mitral stenosis

NYHA: New York Heart Association

PMBC: Percutaneous mitral balloon commissurotomy

SPAP: Systolic pulmonary artery pressure

SUMMARY OF EVIDENCE

2020 ACC/AHA Guideline for the Management of Patients with Valvular Heart Disease ⁽⁶⁾

Study Design: The guidelines were developed by the American College of Cardiology (ACC) and the American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines. The document is based on systematic methods to evaluate and classify evidence, including literature reviews, randomized controlled trials (RCTs), registries, nonrandomized comparative and descriptive studies, case series, cohort studies, systematic reviews, and expert opinion.

Target Population: The guidelines focus on the diagnosis and management of adult patients with valvular heart disease (VHD). The recommendations are applicable to patients with or at risk of developing cardiovascular disease, with a particular emphasis on those in the United States but relevant to patients worldwide.

Key Factors:

Evaluation and Management: The guidelines provide detailed recommendations for the evaluation and management of various types of VHD, including aortic stenosis (AS), aortic regurgitation (AR), bicuspid aortic valve (BAV), mitral stenosis (MS), mitral regurgitation (MR), tricuspid valve disease, and mixed valve disease.

Diagnostic Testing: The guidelines emphasize the importance of diagnostic testing, including transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), cardiac magnetic resonance (CMR) imaging, computed tomography (CT) angiography, and cardiac catheterization.

Medical Therapy: Recommendations for medical therapy include the use of anticoagulants, antiplatelet agents, and other medications for managing symptoms and preventing complications.

Intervention: The guidelines provide criteria for surgical and transcatheter interventions, including valve repair and replacement, based on the severity of the disease and patient-specific factors.

Follow-Up and Monitoring: The document outlines the importance of regular follow-up and monitoring of patients with VHD, including periodic imaging and assessment of ventricular function.

2020 Focused Update of the 2017 Expert Consensus Decision Pathway on the Management of Mitral Regurgitation: A Report of the American College of Cardiology Solution Set Oversight Committee ⁽⁸⁾

Study Design: The guidelines were developed by the American College of Cardiology (ACC) Solution Set Oversight Committee. The document is based on systematic methods to evaluate and classify evidence, including literature reviews, randomized controlled trials (RCTs), registries, nonrandomized comparative and descriptive studies, case series, cohort studies, systematic reviews, and expert opinion.

Target Population: The guidelines focus on the diagnosis and management of adult patients with mitral regurgitation (MR). The recommendations are applicable to patients with or at risk of developing cardiovascular disease, with a particular emphasis on those in the United States but relevant to patients worldwide.

Key Factors:

Evaluation and Management: The guidelines provide detailed recommendations for the evaluation and management of various types of MR, including primary and secondary MR.

Diagnostic Testing: The guidelines emphasize the importance of diagnostic testing, including transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), cardiac magnetic resonance (CMR) imaging, computed tomography (CT) angiography, and cardiac catheterization.

Medical Therapy: Recommendations for medical therapy include the use of anticoagulants, antiplatelet agents, and other medications for managing symptoms and preventing complications.

Intervention: The guidelines provide criteria for surgical and transcatheter interventions, including valve repair and replacement, based on the severity of the disease and patient-specific factors.

Follow-Up and Monitoring: The document outlines the importance of regular follow-up and monitoring of patients with MR, including periodic imaging and assessment of ventricular function.

2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease ⁽⁷⁾

Study Design: The study involved the development of guidelines for the management of valvular heart disease (VHD) by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). The guidelines were developed by a task force of selected experts in the field, representing various ESC subspecialty groups. The process included a comprehensive review of published evidence, diagnostic and therapeutic procedures, and assessment of the risk-benefit ratio.

Target Population: The guidelines focus on patients with valvular heart disease (VHD), including those with aortic regurgitation, aortic stenosis, mitral regurgitation, mitral stenosis, tricuspid regurgitation, tricuspid stenosis, and prosthetic heart valves. The target population encompasses a wide range of valvular heart conditions and patient demographics.

Key Factors:

Recommendations: The guidelines provide evidence-based recommendations for the diagnosis, management, and treatment of VHD, including surgical and transcatheter interventions, medical therapy, and follow-up care.

Diagnostic Testing: The guidelines emphasize the importance of accurate diagnosis, risk assessment, and selection of the most suitable type of intervention. Diagnostic testing includes echocardiography, cardiovascular magnetic resonance imaging (CMR), cardiovascular computed tomography (CCT), and cardiac catheterization.

Medical Therapy: The guidelines recommend medical therapy for heart failure, arrhythmias, pulmonary hypertension, and other related conditions. Specific therapies include beta blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), and pulmonary vasodilators.

Surgical and Transcatheter Interventions: The guidelines provide detailed recommendations for surgical and transcatheter interventions for various valvular heart conditions, including aortic regurgitation, aortic stenosis, mitral regurgitation, mitral stenosis, tricuspid regurgitation, and tricuspid stenosis.

Follow-up Care: The guidelines emphasize the importance of lifelong follow-up care for VHD patients, including regular imaging, exercise testing, and monitoring for complications.

ANALYSIS OF EVIDENCE

Shared Findings ⁽⁶⁻⁸⁾

All three articles emphasize the importance of surgical repair of the mitral valve in patients with mitral regurgitation (MR). They agree on several key points:

- 1. Indications for Surgery:**
 - **Surgery is recommended for symptomatic patients with severe MR, regardless of left ventricular ejection fraction (LVEF).**
 - **Surgery is also recommended for asymptomatic patients with severe MR and left ventricular dysfunction (LVEF <60% or left ventricular end-systolic diameter >40 mm).**
- 2. Preference for Valve Repair:**
 - **Mitral valve repair is preferred over replacement whenever anatomically feasible, as it offers better long-term outcomes and preserves the native valve.**
- 3. Multidisciplinary Approach:**
 - **A multidisciplinary heart team approach is essential for the evaluation and management of patients with MR, ensuring optimal decision-making and treatment outcomes.**

Conclusions ⁽⁶⁻⁸⁾

In summary, all three articles highlight the critical role of surgical repair in managing patients with MR. They share conclusions on the importance of early intervention, preference for valve repair, and the multidisciplinary approach.

POLICY HISTORY

<u>Date</u>	<u>Summary</u>
<u>May 2025</u>	<ul style="list-style-type: none"> ● <u>Edited language to improve acronym use.</u> ● <u>Added third bullet to General Information</u> ● <u>Added Summary of Evidence and Analysis of Evidence</u>
<u>December 2024</u>	<ul style="list-style-type: none"> ● <u>This guideline replaces UM 1099 Mitral Valve Surgery</u> ● <u>Updated references</u> ● <u>Removed redundant indications</u> ● <u>Re-organized indications by condition</u>

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolut Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolut uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolut Clinical Guidelines. Evolut clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolut reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolut Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolut Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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