Medicare Coverage Summary For Transcatheter Edge-To-Edge Repair (TEER)

Coverage Criteria Effective January 19, 2021

The new, finalized Medicare National Coverage Determination (NCD)[1] for the treatment of functional mitral regurgitation (MR) is effective for all hospital discharges from January 19, 2021, onward. For additional questions, please reach out to the Reimbursement Hotline at ReimbursementHelp@Abbott.com.

Functional/Secondary MR Coverage

The tables below provide a summary of coverage for FMR patients. For a complete coverage criterion, please refer to NCD 20.33.

Item	NCD 20.33 Criteria/Requirements[1]
Covered Population	For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication.
Coverage Pathway	TEER with MitraClip™ is covered under Coverage with Evidence Development (CED) and Registry participation is required.
Required Patient Evaluations	For patients with functional MR: Interventional Cardiologist and Heart Failure Cardiologist For patients with degenerative MR: Interventional Cardiologist and Cardiac Surgeon
Coverage Exclusions	Patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure. In patients with untreated severe aortic stenosis.
Heart Failure Cardiologist on the Heart Team	Heart Failure Cardiologist must be experienced in the care and treatment of mitral valve disease. Board certification in Advanced Heart Failure and Transplant Cardiology not required.

Volume Requirements[1]	All TEER Sites
Hospitals	• 20 annual mitral valve (MV) surgeries (or 40 over two years) (50% repair) • ≥300 annual PCIs
Interventional Cardiologists	• ≥50 SH procedures lifetime OR ≥30 left-sided SH annual • ≥20 trans-septal interventions lifetime (10 as primary operator) • Board eligible or certified in interventional cardiology
Cardiac Surgeons	• ≥20 annual mitral valve surgeries (or ≥40 over the past two years) including 50% repair • Board eligible or certified in cardiothoracic surgery or similar foreign equivalent
Imagers	• ≥10 trans-septal guidance procedures and ≥30 SH procedures lifetime • Board eligible or certified in transthoracic and transesophageal echocardiography with advanced training as required for privileging by the hospital where the TEER is performed.

*Note: CMS did not finalize any maintenance volume requirements for transcatheter mitral valve procedures.

Reference

[1]NCD 20.33 and Decision Memo CAG-00438R-Transcatheter Mitral Valve Repair: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=297&NCDId=363&ncdver=1&IsPopup=y&bc=AAAAAAAACAAA&

See Important Safety Information referenced within.

IMPORTANT SAFETY INFORMATION

℞ ONLY MitraClip™ Transcatheter Mitral Valve Repair

Indications for use

- The MitraClip™ G4 System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ☐ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and
  in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.
- The MitraClip™ G4 System, when used with maximally tolerated guideline-directed medical therapy (GDMT), is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) 20% and 50%, and a left ventricular end systolic dimension (LVESD) ☐ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.

Contraindications

The MitraClip G4 System is contraindicated in patients with the following conditions: Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regime; Patients with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity; Active endocarditis of the mitral valve; Rheumatic mitral valve disease; Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

Potential complications and adverse events

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip G4 procedure: Allergic reactions or hypersensitivity to latex, contrast agent, anesthesia, device materials (nickel / titanium, cobalt, chromium, polyester), and drug reactions to anticoagulation, or antiplatelet drugs, Vascular access complications which may require transfusion or vessel repair including: wound dehiscence, catheter site reactions, Bleeding (including ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, vascular occlusion, Emboli (air thrombotic material, implant, device component); Peripheral Nerve Injury; Lymphatic complications; Pericardial complications which may require additional intervention, including: Pericardial effuse on, Cardiac tamponade, Pericarditis; Cardiac complications which may require additional interventions or emergency cardiac surgery, including: Cardiac perforation, Atrial septal defect; Mitral valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single Leaflet Device Attachment (SLDA), Thrombosis, Dislodgement of previously implanted devices, Tissue damage, Mitral valve stenosis, Persistent or residual mitral regurgitation, Endocarditis; Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, and unstable / stable angina); Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post procedure pulmonary embolism); Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction / failure / atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Blood cell disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Hypotension / hypertension; Infection including: Urinary Tract Infection (UTI), Pneumonia, Septicemia; Nausea / vomiting; Chest pain; Dyspnea; Edema; Fever or hyperthermia; Pain; Death; Fluoroscopy, Transesophageal echocardiogram (TEE) and Transthoracic echocardiogram (TTE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation; Esophageal perforation, Gastrointestinal bleeding.

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