FY 2019 HOSPITAL CODING AND PAYMENT GUIDE

MitraClip® Transcatheter Mitral Valve Repair

Effective October 1, 2018

Indication for Use: The MitraClip® 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.

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

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Policy Update

Effective for dates of service beginning October 1, 2016, the Centers for Medicare and Medicaid Services (CMS) has assigned transcatheter mitral valve repair (TMVr) procedures to MS-DRGs 228-229 Other Cardiothroacic Procedures with and without MCCs, respectively. For fiscal year 2019, these MS-DRG assignments remain unchanged.

The Centers for Medicare and Medicaid Services (CMS) provide coverage for transcatheter mitral valve repair (TMVr) under Coverage with Evidence Development.[1]

Among the coverage criteria specified in this National Coverage Determination (NCD):

- TMVr must be performed by an interventional cardiologist or a cardiothoracic surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVr as appropriate.
- All TMVr cases must be enrolled in the national transcatheter valve therapy (TVT) registry.

Other institutional and operator requirements apply based on multi-society guidelines. Refer to the NCD Decision Memo and MLN Matters® Number MM9002 for additional details and requirements.[2]

Note that local Medicare Administrative Contractors (MACs) may have additional coverage criteria as published in Local Coverage Determinations or articles.

Additional Information

Abbott is committed to supporting appropriate patient access to the MitraClip® therapy and educating providers on the latest coverage, coding and payment policy.

For additional questions, please contact the Reimbursement Hotline:

800 354 9997

Questions@AskAbbottVascular.com

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

Procedure Codes

ICD-10-PCS PROCEDURE CODE	DESCRIPTOR
02UG3JZ	Supplement mitral valve with Synthetic Substitute, Percutaneous approach
B245ZZ4	Ultrasonography of Left Heart, Transesophageal

For other concomitant conditions, other TEE codes may apply.
Diagnostic cardiac catheterization may also be coded when it is performed for specific evaluation beyond the approach to the procedure. If the cardiac catheterization is part of the approach for the procedure, it may not be coded separately. 3

Diagnosis Codes

Below are the ICD-10-CM codes currently included in the NCD for TMVr.[2] It is the responsibility of the hospital and physician to determine the appropriate diagnosis code(s) for each patient. As discussed above, participation in the TVT Registry is a requirement of TMVr coverage. Secondary ICD-10-CM Diagnosis Code Z00.6 should be used to denote clinical trial participation for these TMVr claims.[2]

ICD-10-PCS PROCEDURE CODE	DESCRIPTOR
134.0	Nonrheumatic mitral (valve) insufficiency
134.1	Nonrheumatic mitral valve prolapse[4]
Zoo.6	Encounter for exam for normal comparison and control in clinical research program

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Additional Requirements

Additional coding requirements are necessary for TMVr cases enrolled in the TVT Registry

ADDITIONAL REQUIRED INFORMATION	NOTES
NCT 02245763	National Clinical Trial Number is required for cases enrolled in the TVT Registry.[2]
Condition Code 30	Condition Code is required for cases enrolled in the TVT Registry.[2]

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

Hospital Claim Checklist:

The following is a checklist of information that is required to process claims for TMVr procedures with the MitraClip® System per CMS's NCD. It is the responsibility of the hospital or physician to determine appropriate coding for a particular patient and/or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES / MODIFIERS / OTHER	WHEN USED?	INCLUDED	NA
DIAGNOSIS CODES			
I34.0: Nonrheumatic mitral (valve) insufficiency	When appropriate	☐	☐
134.1: Nonrheumatic mitral valve prolapse	All cases	☐	☐
Zoo.6: Encounter for exam for normal comparison and control in clinical research program	All cases	☐	☐
PROCEDURE CODE			
02UG3JZ: Supplement mitral valve with Synthetic Substitute, Percutaneous approach	All cases	☐	☐
B245ZZ4: Ultrasonography of Left Heart, Transesophageal	All cases	☐	☐
CONDITION CODE			
Condition Code 30	All cases	☐	☐
NCT NUMBER			
02245763	All cases*	☐	☐

**NCT number 02245763 is required for cases enrolled in the TVT registry. There is a separate NCT number for the ongoing Investigational Device Exemption (IDE) trial using MitraClip therapy called the COAPT trial. For coding and billing instructions for MitraClip® procedures that are part of this trial please contact the Reimbursement Hotline.*

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

Hospital Inpatient Payment:

Medicare inpatient payments below are effective for FY 2019; October 1, 2018 through September 30, 2019.

Effective October 1, 2016 CMS has assigned TMVr procedures to MS-DRGs 228-229, Other cardiothoracic procedures, with and without MCCs, respectively.

MS-DRG	DESCRIPTOR	FY 2019 NATIONAL BASE PAYMENT[5]
228	Other cardiothoracic procedures with MCC	$40,176
229	Other cardiothoracic procedures without MCC	$28,398

Note that actual hospital payment will vary based on adjustments for factors including geographic differences, teaching status, and disproportionate share of indigent patients.

Private Payers

Private payers use a variety of payment methods for reimbursing inpatient services including case rates, percent of billed charges, DRGs, and device carve outs. Please check with your payer regarding appropriate coding and payment information.

IMPORTANT SAFETY INFORMATION

MITRACLIP CLIP DELIVERY SYSTEMS

INDICATIONS FOR USE

℞ ONLY

The MitraClip® 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.

CONTRAINDICATIONS

The MitraClip® System is contraindicated in DMR patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- **DO NOT use MitraClip® NT outside of the labeled indication. Treatment of non-prohibitive risk DMR patients should be conducted in accordance with standard hospital practices for surgical repair and replacement.**
- MitraClip® is intended to reduce mitral regurgitation. The MitraClip® procedure is recommended to be performed when an experienced heart team has determined that reduction of MR to ≤ 2+ is reasonably expected following the MitraClip®. If MR reduction to ≤ 2+ is not achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from MitraClip® may not occur.
- The MitraClip® Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip® System to avoid user injury.
- Use of the MitraClip® should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and / or reuse may result in infections, malfunction of the device or other serious injury or death.

IMPORTANT SAFETY INFORMATION

MITRACLIP CLIP DELIVERY SYSTEMS

PRECAUTIONS

- Patient Selection:
  - Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
    - 30-day STS predicted operative mortality risk score of
      - ≥ 8% for patients deemed likely to undergo mitral valve replacement or
      - ≥ 6% for patients deemed likely to undergo mitral valve repair
    - Porcelain aorta or extensively calcified ascending aorta.
    - Frailty (assessed by in-person cardiac surgeon consultation)
    - Hostile chest
    - Severe liver disease/cirrhosis (MELD Score >12)
    - Severe pulmonary hypertension (systolic pulmonary artery pressure >2/3 systemic pressure
    - Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.
- Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60mm. MitraClip® should be used only when criteria for clip suitability for DMR have been met.
- The major clinical benefits of MitraClip® are reduction of MR to ≤2+ resulting in reduced hospitalizations, improved quality of life, reverse LV remodeling and symptomatic relief in patients who have no other therapeutic option. No mortality benefit following MitraClip® therapy has been demonstrated.
- The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.
- The heart team may determine an in-person surgical consult is needed to complete the assessment of prohibitive risk. The experienced mitral valve surgeon and heart team should take into account the outcome of this surgical consult when making the final determination of patient risk status.
- For reasonable assurance of device effectiveness, pre-procedural evaluation of the mitral valve and underlying pathologic anatomy and procedural echocardiographic assessment are essential.
- Note the “Use by” date specified on the package.
- Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged.

IMPORTANT SAFETY INFORMATION

MITRACLIP CLIP DELIVERY SYSTEMS

SPECIAL PATIENT POPULATIONS

- *Mitral Valve Etiology*
  Safety and effectiveness of the MitraClip® device has not been established in patients with MR due to underlying ventricular pathology (functional mitral regurgitation or FMR).

- *Pregnancy*
  The MitraClip® device has not been tested in pregnant women. Effects on the developing fetus have not been studied. The risks and reproductive effects are unknown at this time.

- *Gender*
  No safety or effectiveness related gender differences were observed in clinical studies.

- *Ethnicity*
  Insufficient subject numbers prevent ethnicity-related analyses on the clinical safety and effectiveness.

- *Pediatrics*
  Safety and effectiveness of the MitraClip® device has not been established in pediatric patients.

- *Anatomic Considerations*
  For optimal results, the following anatomic patient characteristics should be considered. The safety and effectiveness of the MitraClip® outside of these conditions has not been established. Use outside these conditions may interfere with placement of the MitraClip® Implant or mitral valve leaflet insertion.
  - The primary regurgitant jet is non-commissural. If a secondary jet exists, it must be considered clinically insignificant
  - Mitral valve area ≥ 4.0 cm2
  - Minimal calcification in the grasping area
  - No leaflet cleft in the grasping area
  - Flail width < 15 mm and flail gap < 10 mm

IMPORTANT SAFETY INFORMATION

MITRACLIP CLIP DELIVERY SYSTEMS

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip® procedure.
Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Aneurysm or pseudo-aneurysm; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Arterio-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade / Pericardial Effusion; Chordal entanglement / rupture; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet / anticoagulation agents / contrast media; Dyskinesia; Dyspnea; Edema; Emboli (air, thrombus, MitraClip® Implant); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip® to the intended site; Failure to retrieve MitraClip® System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension / hypertension; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip® Implanterosion, migration or malposition; MitraClip® Implant thrombosis; MitraClip® System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea / vomiting; Pain; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure / atelectasis / insufficiency or failure; Respiratory failure / atelectasis / pneumonia; Septicemia; Shock, Anaphylactic or Cardiogenic; Single leaflet device attachment (SLDA); Skin injury or tissue changes due to exposure to ionizing radiation; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening heart failure; Worsening mitral regurgitation; Wound dehiscence

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References

1. CMS National Coverage Determination for Transcatheter Mitral Valve Repair 20.33.
2. CMS MLN Matters MM9002 Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)
3. AHA Coding Clinic, Third Quarter, 2004, page 10.
4. Per CMS Transmittal 1630, released February 26, 2016
5. Centers for Medicare & Medicaid Services 42 CFR Parts 412, 413, 424, and 495 [CMS-1694-F] RIN 0938-AT27 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and LongTerm Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2019 Rates

Caution: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at eifu.abbottvascular.com or at Manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events

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