

2018 PHYSICIAN CODING AND PAYMENT GUIDE

MitraClip[®] Transcatheter Mitral Valve Repair

Effective January 1, 2018

Indication for Use: The MitraClip[®] System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR \geq 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

Policy Update

Medicare Coverage

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.^{1,2}

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

CPT [†] CODE ³	DESCRIPTOR	CY2018 NATIONAL AVERAGE PAYMENT ⁴	CY2018 TOTAL FACILITY RVUs ⁴
TMVr PROCEDURE WITH IMPLANT			
33418	Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis	\$1,883	52.32
33419	Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; additional prosthesis (es) during same session (List separately in addition to code for primary procedure). (Use 33419 in conjunction with 33418)	\$445	12.36
<p>Angiography, radiological supervision, and interpretation performed to guide TMVr (eg, guiding device placement and documenting completion of the intervention) are included in these codes. Do not report diagnostic right and left heart catheterization procedure codes (93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93530, 93531, 93532, 93533) with 33418 or 33419 when done intrinsic to the valve repair procedure.</p>			
TRANSEOPHAGEAL ECHOCARDIOGRAPHY (TEE) (for intra-procedural monitoring)			
93355*	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri- and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D	\$234	6.49

*Note that 93355 is bundled and not separately payable when reported on the same physician claim as the TMVr with MitraClip® procedure (33418) or with anesthesia services

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

Coding Modifiers and Additional Requirements

Additional coding requirements are necessary for TMVr cases enrolled in the TVT Registry and for cases involving two surgeons/co-surgeons.

MODIFIER	NOTES
-Q0/-Q1	Use for physician claims for cases enrolled in the TVT Registry.
-62	Use for physician claims for cases where two surgeons / co-surgeons perform TMVR. Note that in scenarios where co-surgeon participation is medically necessary, the submission of supporting documentation is required. ²
-80/-82	Use for assistant surgeon claims for TMVR. Append modifier to assistant surgeon claims; do not append modifier to primary surgeon claims. Use -80 when TMVR is performed at non-teaching community hospitals without surgery residents. Use -82 for when TMVR is performed at teaching hospitals with surgery residents; -82 indicates qualified surgery resident unavailable. Documentation regarding medical necessity required.
ADDITIONAL REQUIRED INFORMATION	NOTES
NCT 02245763	National Clinical Trial Number is required for cases enrolled in the TVT Registry. ²

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

Coding for Co-surgeons

TMVr s covered by Medicare when performed by a single operator, or by co-surgeons as clinically appropriate. Per the TMVr NCD (20.33), “The heart team’s interventional cardiologist or a cardiothoracic surgeon must perform the TMVr.

Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVr as appropriate.”²

The Physician Final Rule 2017 states that the -62 modifier for TMVr has a status indicator of one (1) which signifies that co-surgeons may be paid.

- Both surgeons use the same CPT code and apply the -62 modifier. Each surgeon submits a separate claim for their professional services.
- CMS’ general policy regarding co-surgeons, and medical necessity thereof, apply to TMVr procedures. At this time, there are no TMVr-specific criteria or guidance for co-surgeons, nor do we anticipate that CMS will develop such TMVr-specific direction regarding co-surgeons.
- Each surgeon’s role must be clearly defined in the operative notes. See below table for considerations.
- Local Medicare Administrative Contractors (MAC) will determine the medical necessity of co-surgeons performing TMVr based on the documentation submitted. MACs would likely expect each co-surgeon to produce their own procedure / operative report detailing their role in the procedure and clinical decision-making, as well as the rationale for each surgeon participating in the procedure.
- While co-surgeons are typically expected to be from different specialties, co-surgeons from the same specialty may be paid at carrier discretion.

CONSIDERATIONS	EXAMPLE
Note which tasks you completed.	“I advanced a wire from the right femoral vein to the superior vena cava for placement of the transeptal sheath and needle.”
Note which tasks your co-surgeon completed.	“Dr. Smith advanced the mitral valve repair device and delivery system through the guide to the left atrium.”
Avoid using the term “we.”	Instead of “We positioned the clip” consider, “I advanced the implant into the LV, by advancing the delivery catheter handle as Dr. Smith assisted in positioning the Clip below the valve by maintaining our anterior/posterior position with the guide.”

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

Diagnosis Codes

Below are the diagnosis codes currently included in the NCD for TMVr.² It is the responsibility of the 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 diagnosis code Zoo.6 should be used to denote clinical trial participation for these TMVr claims.²

ICD-10-CM DIAGNOSIS CODE	CODE DESCRIPTOR
I34.0	Nonrheumatic mitral (valve) insufficiency
I34.1	Nonrheumatic mitral valve prolapse ⁶
Zoo.6	Encounter for exam for normal comparison and control in clinical research program

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. Policies vary considerably for co-surgeons. Payers should be consulted in advance of the procedure to verify terms and conditions. Please check with your payer regarding appropriate coding and payment information.

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

For Implanting Physician(s):

This checklist is provided as a visual summary of the information contained in this coding guide. Please see references at the end of this guide. It is the responsibility of the physician to determine the appropriate diagnosis code (s) for each patient. Codes listed below are for reference only.

CODES / MODIFIERS / OTHER		WHEN USED?	INCLUDED	NA
Diagnosis Codes	I34.0 / I34.1 Nonrheumatic mitral valve disorders ⁶	When appropriate	<input type="checkbox"/>	<input type="checkbox"/>
	Z00.6 Examination of a participant in a clinical trial	All cases	<input type="checkbox"/>	<input type="checkbox"/>
CPT Codes	33418 Transcatheter mitral valve repair; initial prosthesis	All cases	<input type="checkbox"/>	<input type="checkbox"/>
	+33419 Transcatheter mitral valve repair; add'l prosthesis(es)	Cases where two or more clips are implanted	<input type="checkbox"/>	<input type="checkbox"/>
CPT Code Modifiers	-Q0/Q1 Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All cases	<input type="checkbox"/>	<input type="checkbox"/>
	-62 -62 When two surgeons work together as primary surgeons performing distinct part(s) of a procedure.	When two surgeons/ co-surgeons perform the procedure. Supporting documentation is required to show medical necessity for co-surgeons	<input type="checkbox"/>	<input type="checkbox"/>
NCT Number	02245763	All cases*	<input type="checkbox"/>	<input type="checkbox"/>

**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

For Echocardiographer

This checklist is provided as a visual summary of the information contained in this coding guide. Please see references at the end of this guide. It is the responsibility of the physician to determine the appropriate diagnosis code (s) for each patient. Codes listed below are for reference only.

CODES / MODIFIERS / OTHER		WHEN USED?	INCLUDED	NA
Diagnosis Codes	I34.0 / I34.1 nonrheumatic mitral valve disorders ⁶	When appropriate	<input type="checkbox"/>	<input type="checkbox"/>
	Z00.6 Examination of a participant in a clinical trial	All cases	<input type="checkbox"/>	<input type="checkbox"/>
CPT Codes	93355 TEE for intra procedural monitoring	All cases	<input type="checkbox"/>	<input type="checkbox"/>
CPT Code Modifiers	-Q0/Q1 Investigational / Routine clinical service provided in a clinical research study that is in an approved clinical research study.	All cases	<input type="checkbox"/>	<input type="checkbox"/>
NCT Number	02245763	All cases*	<input type="checkbox"/>	<input type="checkbox"/>

**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.*

IMPORTANT SAFETY INFORMATION

MITRACLIP CLIP DELIVERY SYSTEMS

Rx ONLY INDICATIONS FOR USE

The MitraClip® System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR \geq 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 \leq 2+ is reasonably expected following the MitraClip®. If MR reduction to \leq 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
 - $\geq 8\%$ for patients deemed likely to undergo mitral valve replacement or
 - $\geq 6\%$ 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 $> 60\text{mm}$. 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 $\leq 2+$ 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. CPT Copyright 2017 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.
4. Centers for Medicare & Medicaid Services 42 CFR Parts 405, 410, 414, 424, and 425 [CMS-1676-F]. CY2018 relative value units and related information used in determining final Medicare payments. Rates are calculated using a 2018 Conversion Factor of 35.9996
5. National Correct Coding Initiative Policy Manual for Medicare Services, Chapter II, Revision 1/1/2017.
6. Per CMS Transmittal 1630, released February 26, 2016
7. Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD). CMS Manual System. Pub 100-04 Medicare Calims Processing. Transmittal 3241.

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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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