POLICY UPDATE

Effective for dates of service beginning on January 1, 2015, the American Medical Association approved the creation of two new category I CPT codes for the MitraClip® therapy and a new interventional echocardiography category I CPT code. Providers are encouraged to consult the Medicare National Coverage Determination for TMVR (20.33) and related Centers for Medicare and Medicaid Services (CMS) publications, their local Medicare contractors and other payers to understand their specific coverage criteria and coding guidelines.

Effective for dates of service beginning on August 7, 2014, the CMS finalized a national Medicare coverage policy for TMVR under Coverage with Evidence Development. 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.

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

CMS has finalized their proposal to continue New Technology Add-on Payments (NTAP) for the MitraClip® therapy as part of the FY2016 Inpatient Prospective Payment System Final Rule. Effective for dates of service beginning October 1, 2014 CMS approved up to $15,000 per MitraClip® case above and beyond the normal DRG payment. Incremental reimbursement with NTAP is calculated as either (a) 50% of the incremental cost of the new technology above the DRG payment; or, (b) $15,000, whichever is lower. Congress and CMS originally established NTAP in 2001 under Medicare to support hospital adoption of new technologies. Please refer to the MitraClip Hospital Coding and Payment Guide for more details.

In addition, CMS is excluding the NTAP for MitraClip® from expenditure targets for cases included in the Bundled Payments for Care Improvement Initiative (BPCI). This decision will ensure hospitals are not penalized financially by this value-based payment program for adopting the MitraClip® technology.

NTAP Requirements:
1. The technology must be truly novel and FDA-approved within two to three years.
2. It must represent a substantial clinical improvement for Medicare beneficiaries.
3. It must meet a high cost threshold established by CMS.

Indication: The MitraClip Clip Delivery 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.

See Important Safety Information Referenced Within.
2016 PHYSICIAN CODING & PAYMENT

Medicare physician payment is effective for calendar year 2016, January 1 through December 31.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Descriptor</th>
<th>CY2016 National Average Payment</th>
<th>CY2016 Total Facility RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>33418</td>
<td>Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis</td>
<td>$1,871</td>
<td>52.26</td>
</tr>
<tr>
<td>33419</td>
<td>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 33418 in conjunction with 33419)</td>
<td>$440</td>
<td>12.30</td>
</tr>
</tbody>
</table>

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.

**Transesophageal Echocardiography (TEE) (for intra-procedural monitoring)**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>CY2016 National Average Payment</th>
<th>CY2016 Total Facility RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>93355</td>
<td>Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcathether 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</td>
<td>$230</td>
<td>6.43</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Q0/-Q1</td>
<td>Use for physician claims for cases enrolled in the TVT Registry.</td>
</tr>
<tr>
<td>-62</td>
<td>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.</td>
</tr>
<tr>
<td>-80 / -82</td>
<td>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.</td>
</tr>
</tbody>
</table>

Additional Required Information:

<table>
<thead>
<tr>
<th>Notes</th>
<th>National Clinical Trial Number is required for cases enrolled in the TVT Registry.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT 02245763</td>
<td></td>
</tr>
</tbody>
</table>

TMVR is 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.”

On April 24, 2015, CMS issued updated Medicare Claims Processing Instructions for the TMVR NCD to remove confusing instructions about the -62 modifier.

- Previously, Medicare indicated claim lines for two surgeons/co-surgeons billed without modifier -62 shall be returned. This language has now been removed.

The Physician Final Rule 2015 states that the -62 modifier for TMVR has a status indicator of one (1) which signifies that co-surgeons may be paid. However, documentation is required to support the medical necessity of two surgeons performing the TMVR procedure.

- 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.

- 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.

- Co-surgeons are not mandatory for TMVR CPT codes.
Diagnosis Codes

ICD-10-CM diagnosis codes are used by physicians to document the clinical condition of the patient undergoing the procedure. Below are the diagnosis codes currently included in the NCD for TMVR. 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 Z00.6 should be used to denote clinical trial participation for these TMVR claims.

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code (Effective October 1, 2015)</th>
<th>Code Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>I34.0</td>
<td>Nonrheumatic mitral (valve) insufficiency</td>
</tr>
<tr>
<td>I34.8</td>
<td>Other nonrheumatic mitral valve disorders</td>
</tr>
<tr>
<td>Z00.6</td>
<td>Encounter for exam for normal comparison and control in clinical research program</td>
</tr>
</tbody>
</table>

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.

PHYSICIAN CLAIM CHECKLIST

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.

For Implanting Physician(s):

<table>
<thead>
<tr>
<th>Codes / Modifiers / Other</th>
<th>When Used?</th>
<th>Included</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis Codes*</td>
<td>I34.0 / I34.8 Nonrheumatic mitral valve disorders</td>
<td>When appropriate</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Z00.6</td>
<td>Examination of a participant in a clinical trial</td>
<td>All TMVR cases</td>
</tr>
<tr>
<td>CPT Codes</td>
<td>33418</td>
<td>Transcatheter mitral valve repair; initial prosthesis</td>
<td>All TMVR cases</td>
</tr>
<tr>
<td></td>
<td>+33419</td>
<td>Transcatheter mitral valve repair; add’l prosthesis(es)</td>
<td>TMVR cases where two or more clips are implanted</td>
</tr>
<tr>
<td>CPT Code Modifiers</td>
<td>-Q0/Q1</td>
<td></td>
<td>All TMVR cases</td>
</tr>
<tr>
<td></td>
<td>-62</td>
<td>When two surgeons / co-surgeons perform TMVR. Supporting documentation is required to show medical necessity for co-surgeons</td>
<td></td>
</tr>
</tbody>
</table>

NCT Number 02245763

All TMVR cases

Note: Short descriptions used for code descriptions.
*It is the responsibility of the physician to determine the appropriate diagnosis code(s) for each patient. Codes provided are for reference only.

For Echocardiographer:

<table>
<thead>
<tr>
<th>Codes / Modifiers / Other</th>
<th>When Used?</th>
<th>Included</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis Codes*</td>
<td>I34.0 / I34.8 Nonrheumatic mitral valve disorders</td>
<td>When appropriate</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Z00.6</td>
<td>Examination of a participant in a clinical trial</td>
<td>All TMVR cases</td>
</tr>
<tr>
<td>CPT Codes</td>
<td>93355</td>
<td>TEE for intra-procedural monitoring</td>
<td>All TMVR cases</td>
</tr>
<tr>
<td>CPT Code Modifiers</td>
<td>-Q0/Q1</td>
<td></td>
<td>All TMVR cases</td>
</tr>
</tbody>
</table>

NCT Number 02245763

All TMVR cases

Note: Short descriptions used for code descriptions.
*It is the responsibility of the physician to determine the appropriate diagnosis code(s) for each patient. Codes provided are for reference only.
Abbott Vascular 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

Disclaimer: The information provided in this document was obtained from third-party sources and is subject to change without notice as a result of changes in reimbursement laws, regulations, rules, policies, and payment amounts. All content is informational only, general in nature, and does not cover all situations or all payers’ rules and policies. 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. A determination of medical necessity is a prerequisite that Abbott Vascular assumes will have been made prior to assigning codes or requesting payments. Any codes provided are examples of codes that specify some procedures or which are otherwise supported by prevailing coding practices. They are not necessarily correct coding for any specific procedure using Abbott Vascular’s products. Hospitals and physicians should consult with appropriate payers, including Medicare Administrative Contractors, for specific information on proper coding, billing, and payment levels for healthcare procedures. Abbott Vascular makes no express or implied warranty or guarantee that (i) this list of codes and narratives in this document is complete or error-free, (ii) the use of this information will prevent difference of opinions or disputes with payers, (iii) these codes will be covered or (iv) the provider will receive the reimbursement amounts set forth herein. Reimbursement policies can vary considerably from one region to another and may change over time. The FDA-approved/cleared labeling for all products may not be consistent with all uses described herein. This document is in no way intended to promote the off-label use of medical devices. This content is not intended to instruct hospitals and/or physicians on how to use medical devices or bill for healthcare procedures.

1 CMS. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015. 42 CFR Parts 403, 405, 410, 411, 412, 413, 414, 425, 489, 495, and 498. CMS-1612 FC.
3 Centers for Medicare & Medicaid Services. 42 CFR Part 412 [CMS-1632-F and IFC, CMS-1632-CN2] RIN--0938--AS41 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Fiscal Year 2016 Rates.
4 Email communication from Center for Medicare and Medicaid Innovation (CMMI) staff to AdvaMed; formal announcement anticipated.
5 CPT Copyright 2015 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.
7 CMS MLN Matters MM9002 Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)
MITRACLIP® CLIP DELIVERY SYSTEM INDICATION FOR USE

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

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

WARNINGS

- DO NOT use MitraClip 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 Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgeons 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 re-use may result in infections, malfunction of the device or other serious injury or death.
- Inspect all product prior to use. DO NOT use if the package is opened or damaged.

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
    - ≥8% for patients deemed likely to undergo mitral valve repair

- Porcelain aorta or extensively calcified ascending aorta
- Frazil (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 circumstances, 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.

- Evaluate data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LV EF < 20% or an LVEF > 60mm. MitraClip should be used or not as an option 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 with 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.
- The inside of the outer pouch is not a sterile barrier. The inside of the outer pouch is not a sterile barrier. The inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

- Note the “Use by” date specified on the package.

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); Anuria or pseudo-anuria; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Artero-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade/Pericardial Effusion; Chordal entanglement/rupture; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombosis (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet/anticoagulation agents/contrast media; Dyskinesia; Dyspnea; Edema; Emboli (air, thrombus, MitraClip Device); 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; Hypersensitivity/hypersensitivity; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip erosion; migration or malposition; MitraClip Device thrombosis; MitraClip System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/vomiting; Pain; Peripheral ischemia; Prolonged anaphylaxis; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal 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

STEERABLE GUIDE CATHERET INDICATION FOR USE

The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

CONTRAINDICATIONS

- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

WARNINGS

- 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 to avoid user injury.
- Use the Steerable Guide Catheter with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgeons and immediate access to a cardiac operating room.
- The Steerable Guide Catheter is designed for single use only. Cleaning, re-sterilization and/or re-use may result in infections, malfunction of the device or other serious injury or death.
- Patients with the following considerations in whom the Steerable Guide Catheter is used may have an increased risk of having a serious adverse event which may be avoided with proactive evaluation and proper device usage:
  - Previous interatrial septal patch or prosthetic atrial septal defect (ASD) closure device which could result in significant difficulty in visualization or technical challenges during transseptal puncture and/or introducing the SCS into the left atrium.
  - Known or suspected unstable angina or myocardial infarction within the last 12 weeks could increase the procedural morbidity and mortality, due to increased hemodynamic stress secondary to general anesthesia.
  - Patients with active infection have an increased risk of developing an intraoperative and/or postoperative infection, such as sepsis or soft tissue abscess.
  - Known or suspected left atrial myxoma could result in thromboembolism and tissue injury due to difficulty with device positioning.
  - Recent cerebrovascular event (CVA) may increase the procedural morbidity associated with a transcatheter intervention, such as recurrent stroke.

PRECAUTIONS

NOTE the “Use by” date specified on the package. Inspect all product prior to use. DO NOT use if package is opened or damaged. The inside of the outer pouch is not a sterile barrier. The inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

Prior to use, please refer to the Instructions for Use at www.abbottvascular.com/ifu for more information on indications, contraindications, warnings, precautions, and adverse events.