POLICY UPDATE

Effective for dates of service beginning October 1, 2016, the Centers for Medicare and Medicaid Services (CMS) has reassigned transcatheter mitral valve repair (TMVR) procedures to reconfigured MS-DRGs 228-229 Other Cardiothoracic Procedures with and without MCCs, respectively.

This MS-DRG reassignment results in a 100% increase in base payment rates. Actual DRG payments will vary based on area wage rates, Graduate Medical Education, Disproportionate Share, and other payments.

Effective October 1, 2016, MitraClip therapy procedures are no longer eligible for New Technology Add-on Payments.

Congress and CMS originally established NTAP in 2001 under Medicare to support hospital adoption of new technologies. CMS approved NTAP for the MitraClip therapy after determining that it was a novel, high cost technology that provides a substantial clinical improvement. NTAP was granted for a period of two years, from FY2014-FY2016.

CMS provides coverage for TMVR therapy under a Coverage with Evidence Development framework.

Among the different 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 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.

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.
HOSPITAL INPATIENT CODING

Procedure Codes

The ICD-10-PCS codes for TMVR procedures with the MitraClip® System are as follows:

<table>
<thead>
<tr>
<th>ICD-10-PCS Procedure Code</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>02UG3JZ</td>
<td>Supplement mitral valve with Synthetic Substitute, Percutaneous approach</td>
</tr>
<tr>
<td>B245ZZ4</td>
<td>Ultrasonography of Left Heart, Transesophageal</td>
</tr>
</tbody>
</table>

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.

Diagnosis Codes

Below are the ICD-10-CM codes currently included in the NCD for TMVR. 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.

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

Additional Requirements

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

<table>
<thead>
<tr>
<th>Additional Required Information</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT 02245763</td>
<td>National Clinical Trial Number is required for cases enrolled in the TVT Registry.</td>
</tr>
<tr>
<td>Condition Code 30</td>
<td>Condition Code is required for cases enrolled in the TVT Registry.</td>
</tr>
</tbody>
</table>

HOSPITAL INPATIENT PAYMENT

Medicare inpatient payments below are effective for FY 2017: October 1, 2016, through September 30, 2017. Effective October 1, 2016 CMS has reassigned TMVR procedures to reconfigured MS-DRGs 228-229, Other cardiothoracic procedures, with and without MCCs, respectively. This reassignment results in 100% increase in base MS-DRG payment rates.

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Descriptor</th>
<th>FY2017 National Base Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>228</td>
<td>Other cardiothoracic procedures with MCC</td>
<td>$42,262</td>
</tr>
<tr>
<td>229</td>
<td>Other cardiothoracic procedures without MCC</td>
<td>$28,302</td>
</tr>
</tbody>
</table>

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.

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.

<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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I34.0: Nonrheumatic mitral (valve) Insufficiency</td>
<td>When appropriate</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I34.1: Nonrheumatic mitral valve prolapse</td>
<td>When appropriate</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Z00.6: Encounter for exam for normal comparison and control in clinical research program</td>
<td>All cases</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Procedure Code</td>
<td></td>
<td></td>
<td></td>
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<td>02UG3JZ: Supplement mitral valve with Synthetic Substitute, Percutaneous approach</td>
<td>All cases</td>
<td>☐</td>
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<td>All cases</td>
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<td>All cases</td>
<td>☐</td>
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</tr>
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<td>NCT Number 02245763</td>
<td>All cases*</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

*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.

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

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1 CMS 42 CFR Parts 405, 412, 413, and 485 [CMS-1635-F; CMS-16644-F; CMS-1632-P2] RIN 0938-AS77; 0938-AS88; 0938-AS41 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates.
3 CMS National Coverage Determination for Transcatheter Mitral Valve Repair 20.33.
4 CMS MLN Matters MM9002 Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)
6 Per CMS Transmittal 1630, released February 26, 2016
The MitraClip® NT 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 cardiologist 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® NT 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 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® NT is intended to reduce mitral regurgitation. The MitraClip® NT 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® NT. 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® NT may not occur.
- The MitraClip® NT 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 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® NT System to avoid user injury.
- Use of the MitraClip® NT 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.

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.
- Evaluation data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60mm. MitraClip® NT should be used only when criteria for clip suitability for DMR have been met.
- The major clinical benefits of MitraClip® NT 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® NT therapy has been demonstrated.
- The heart team should include a cardiac 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 “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.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip® NT procedure.

- Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Anemia 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® NT Device); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip® NT to the intended site; Failure to retrieve MitraClip® NT 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® NT erosion, migration or malposition; MitraClip® NT Device thrombosis; MitraClip® NT System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/ vomiting; Pain; Peripheral ischemia; Prolonged anemia; Prolonged ventilation; Pulmonary congestion; Pulmonary thromboembolism; 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

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