Transcatheter Mitral Valve Repair "MitraClip®"

National Coverage Determination (NDC) Background

- October 24, 2013: Per the August 7, 2014 Decision Memo, the FDA approved the first TMVR device. Abbott Vascular's MitraClip® was approved "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."
- August 7, 2014: Original Decision Memo for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438N)
- August 7, 2014: Effective date for National Coverage Determination (NCD) for Transcatheter Mitral Valve Repair (TMVR) (20.33)

August 14, 2019: At the request of the Society of Thoracic Surgeons (STS), the American College of Cardiology (ACC), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography & Interventions (SCAI), CMS opened a National Coverage Analysis (NCA) Tracking Sheet for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R). The expected release of a Proposed Decision Memo is February 14, 2020.

National Coverage Analysis Issue

TMVR is used in the treatment of mitral regurgitation (MR). There are two types of MR.

- Degenerative (primary) MR involved structural abnormality, and
- Functional (secondary) MR is a distinct condition that generally results from left ventricular dysfunction.

Abbott Vascular's MitraClip® is currently the only FDA-approved TMVR device. The procedure involves clipping together a portion of the mitral valve leaflets as a treatment for reducing MR to improve recovery of the heart from overwork, improve function and potentially halt the progression of heart failure.

Currently, the NCD establishes coverage for the treatment of significant symptomatic degenerative MR. This analysis will primarily focus on TMVR for the treatment of significant symptomatic functional MR.

Indications and Limitations of Coverage for NCD 20.33

CMS covers TMVR for degenerative (primary) MR under Coverage with Evidence Development (CED) with the following conditions:

A. **Treatment of significant symptomatic degenerative MR** when furnished according to an FDA-approved indication and when all of the following conditions are met:

1. The procedure is furnished with a complete TMVR system that has received FDA premarket approval (PMA) for that system's FDA-approved indication.
2. **Both** a **cardiothoracic surgeon** experienced in mitral valve surgery **and a cardiologist** experienced in mitral valve disease have independently examined the patient face-to-face and

evaluated the patient's suitability for mitral valve surgery and determination of prohibitive risk; **and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.**

3. The patient (pre-operatively and post-operatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

   TMVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

   a. On-site active valvular heart disease surgical program with **≥ 2 hospital-based cardiothoracic surgeons experienced in valvular surgery**;
   b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering catheterization laboratory-quality imaging,
   c. Non-invasive imaging expertise including transthoracic/transesophageal/3D echocardiography, vascular studies, and cardiac CT studies;
   d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications;
   e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures;
   f. Adequate outpatient clinical care facilities
   g. Appropriate volume requirements per the applicable qualifications below.

There are institutional and operator requirements for performing TMVR. The hospital must have the following:

   a. A surgical program that performs ≥ 25 total mitral valve surgical procedures for severe MR per year of which at least 10 must be mitral valve repairs;
   b. An interventional cardiology program that performs ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year, with acceptable outcomes for conventional procedures compared to National Cardiovascular Data Registry (NCDR) benchmarks;
   c. The heart team must include:
      1. An interventional cardiologist(s) who:
         - performs ≥ 50 structural procedures per year including atrial septal defects (ASD), patent foramen ovale (PFO) and trans-septal punctures; and,
         - must receive prior suitable training on the devices to be used; and,
         - must be board-certified in interventional cardiology or board-certified/eligible in pediatric cardiology or similar boards from outside the United States;
      2. Additional members of the heart team, including: cardiac echocardiographers, other cardiac imaging specialists, heart valve and heart failure specialists, electrophysiologists, cardiac anesthesiologists, intensivists, nurses, nurse practitioners, physician assistants, data/research coordinators, and a dedicated administrator;
   d. All cases must be submitted to a single national database;

e. Ongoing continuing medical education (or the nursing/technologist equivalent) of 10 hours per year of relevant material;
f. The cardiothoracic surgeon(s) must be board-certified in thoracic surgery or similar foreign equivalent.

4. 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.
5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TMVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient-, practitioner-, and facility-level variables that predict each of these outcomes:
    i. All-cause mortality;
    ii. Stroke;
    iii. Repeat mitral valve surgery or other mitral procedures;
    iv. Worsening MR;
    v. Transient ischemic events (TIAs);
    vi. Major vascular events;
    vii. Renal complications;
    viii. Functional capacity;
    ix. Quality of Life (QoL).

B. This section of the NCD outlines what a hospital must do when TMVR for MR is performed for uses that are not expressly listed as an FDA-approved indication when performed within an FDA-approved randomized controlled trial.

C. This section details the standards of scientific integrity and relevance to the Medicare population that must be adhered to for CMS-approved clinical trials and registries.

The TMVR Registry and Clinical Study Approvals are posted on the CMS CED website at: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TMVR.html.

Nationally Non-Covered Indications in NCD 20.33 **TMVR is non-covered for the treatment of MR when not furnished under CED according to the criteria outlined in the NCD. TMVR used for the treatment of any non-MR indications are non-covered.**

Hospital Inpatient Only Procedure

The TMVR procedure is on the Medicare "Inpatient-Only" Procedure (IPO) List and is not an approved procedure in the outpatient hospital setting for Medicare beneficiaries. The Medicare IPO list defines services that support an inpatient admission and Part A payment as appropriate, regardless of the expected length of stay. CMS has directed Medicare Administrative Contractors (MACs) to approve these cases so long as other requirements (i.e. NCD indications and limitations of coverage) are met.

ICD-10 Procedure and Diagnosis Codes, Claims Requirements and MS-DRG Assignment for TMVR

This procedure is covered under Coverage with Evidence Development (CED). This means the claims must include a secondary diagnosis code, condition code, and value code related to the clinical trial/registry.

- **ICD-10 Procedure Codes (one of the following):**
  - 02UG3JZ (Supplemental Mitral Valve with Synthetic Substitute, Percutaneous approach)
  - 02QG3ZE (Repair Mitral Valve created from Left Atrioventricular Valve, Percutaneous approach)
  - 02QG4ZE (Repair Mitral Valve created from Left Atrioventricular Valve, Percutaneous Endoscopic Approach)
  - 02UG37E (Supplement Mitral Valve created from Left Atrioventricular Valve with Autologous Tissue Substitute, Percutaneous Approach)
  - 02UG38E (Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Percutaneous Approach)
  - 02UG3JE (Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Percutaneous Approach)
  - 02UG3KE (Supplement Mitral Valve created from Left Atrioventricular Valve with Nonautologous Tissue Substitute, Percutaneous Approach)
  - 02UG3KZ (Supplement Mitral Valve with Nonautologous Tissue Substitute, Percutaneous Approach)
  - 02UG47E (Supplement Mitral Valve created from Left Atrioventricular Valve with Autologous Tissue Substitute, Percutaneous Endoscopic Approach)
  - 02UG48E (Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach)
  - 02UG48E (Supplement Mitral Valve created from Left Atrioventricular Valve with Zooplastic Tissue, Percutaneous Endoscopic Approach),
  - 02UG4JE (Supplement Mitral Valve created from Left Atrioventricular Valve with Synthetic Substitute, Percutaneous Endoscopic Approach)
  - 02UG4KE(Supplement Mitral Valve created from Left Atrioventricular Valve with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach)
  - 02WG37Z (Revision of Autologous Tissue Substitute in Mitral Valve, Percutaneous Approach)
  - 02WG38Z (Revision of Zooplastic Tissue in Mitral Valve, Percutaneous Approach)
  - 02WG3JZ (Revision of Synthetic Substitute in Mitral Valve, Percutaneous Approach)
  - 02WG3KZ (Revision of Nonautologous Tissue Substitute in Mitral Valve, Percutaneous Approach)
- **Covered Primary ICD-10 Diagnosis Code (one of the following):**
  - I34.0 – Nonrheumatic mitral (valve) insufficiency, or
  - I34.1 – Nonrheumatic mitral valve prolapse

Second Quarter 2019 *Coding Clinic* guidance advises that ICD-10-CM assumes aortic and mitral valve insufficiency is rheumatic in nature when it is not described as nonrheumatic. Documentation in the medical record should clearly specify if the valve insufficiency is nonrheumatic or rheumatic as this procedure is approved for nonrheumatic mitral insufficiency.

- **Secondary diagnosis code**: Z00.6 – Encounter for examination for normal comparison and control in clinical research program
- **Condition Code:** 30 – Qualified Clinical Trial
- **Value Code D4 and corresponding 8-digit clinical trial number** (Clinical trial and/or registry numbers can be found on the Medicare's CED website.

MS-DRG Assignment Change for FY 2020

Prior to October 1, 2019, this procedure groups to the following MS-DRG pair:

- MS-DRG 228: Other Cardiothoracic Procedures with MCC, or
- MS-DRG 229: Other Cardiothoracic Procedures without MCC

In the FY 2020 IPPS Final Rule, CMS finalized regrouping these claims to a new MS-DRG Pair. Effective October 1, 2019, the MitraClip Procedure will group to the following MS-DRG pair:

- MS-DRG 266: Endovascular Cardiac Valve Replacement with MCC, or
- MS-DRG 267: Endovascular Cardiac Valve Replacement without MCC.

Medical Management Plus Inc.
1900 20th Avenue South Suite 220
Birmingham, AL 35209
(205)941-1105