

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services



NEW product from the Medicare Learning Network® (MLN)

- [“Complying With Medical Record Documentation Requirements”](#) Fact Sheet, ICN 909160, Downloadable

MLN Matters® Number: MM9002 Revised

Related Change Request (CR) #: CR 9002

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Effective Date: August 7, 2014

Related CR Transmittal #: R178NCD and R3241CP

Implementation Date: April 6, 2015

### Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)

Note: This article was revised on April 26, 2015, due to the release of an updated Change Request (CR). That CR removed the text concerning billing TMVR for MR with modifier -62 (and from page 5 below). The CR Release Date, transmittal number and link to the transmittal was also changed. All other information remains the same.

#### Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for Transcatheter Mitral Valve Repair (TMVR) services provided to Medicare beneficiaries.

#### Provider Action Needed

Effective for claims with dates of service furnished on or after August 7, 2014, the Centers for Medicare & Medicaid Services (CMS) will reimburse claims for TMVR for Mitral Regurgitation (MR) when furnished under Coverage with Evidence Development (CED).

#### Disclaimer

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TMVR is non-covered for the treatment of MR when not furnished under CED according to the above-noted criteria. TMVR used for the treatment of any non-MR indications are non-covered by Medicare.

## Background

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TMVR is a new technology for use in treating MR. MR occurs when the leaflets of the mitral valve do not close properly and blood flows from the left ventricle back into the left atrium, causing the heart to work harder to pump. This, in turn, causes enlargement of the left ventricle and can lead to potential heart failure.

Abbott's MitraClip, the only U.S. Food and Drug Administration (FDA)-approved TMVR device, involves clipping together a portion of the mitral valve leaflets. This is performed under general anesthesia, with delivery of the device typically through a percutaneous transvenous approach, via echocardiographic and fluoroscopic guidance. The procedure is performed in a cardiac catheterization laboratory or hybrid operating room/cardiac catheterization laboratory with advanced quality imaging. TMVR is covered for uses not listed as an FDA-approved indication when performed in approved clinical studies which meet certain study question requirements. The TMVR procedure must be performed by an interventional cardiologist or cardiac surgeon, or they may jointly participate in the intraoperative technical aspects, as appropriate.

On August 7, 2014, CMS issued a final decision memorandum covering TMVR for MR under CED for the treatment of MR when furnished for an FDA-approved indication with an FDA-approved device as follows:

- Treatment of significant, symptomatic, degenerative MR when furnished according to an FDA-approved indication, and all CMS coverage criteria are met; and
- TMVR for MR uses not expressly listed as FDA-approved indications but only within the context of an FDA-approved, randomized clinical trial that meets all CMS coverage criteria.

CED requires that each patient be entered into a qualified national registry. In addition, prior to receiving TMVR, face-to-face examinations of the patient are required by a cardiac surgeon and a cardiologist experienced in mitral valve surgery to evaluate the patient's suitability for TMVR and determination of prohibitive risk, with documentation of their rationale.

The NCD lists the criteria that must be met prior to beginning a TMVR program and after a TMVR program is established. No NCD existed for TMVR for MR prior to August 7, 2014, and TMVR is non-covered outside CED or for non-MR indications. The Web address for accessing the NCD transmittal is available in the "Additional Information" section at the end of this article.

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CR9002 revises the “Medicare Claims Processing Manual,” Chapter 32, Section 340 (Transcatheter Mitral Valve Repair (TMVR)), and the “National Coverage Determinations (NCD) Manual,” Chapter 20, Section 20.33 (Transcatheter Mitral Valve Repair (TMVR)) which are included in CR9002.

**Based on the NCD, TMVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:**

- On-site active valvular heart disease surgical program with >2 hospital-based cardiothoracic surgeons experienced in valvular surgery;
- 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;
- Non-invasive imaging expertise including transthoracic/transesophageal/3D echocardiography, vascular studies, and cardiac CT studies;
- Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications;
- Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures;
- Adequate outpatient clinical care facilities; and
- Appropriate volume requirements per the applicable qualifications below.

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

- A surgical program that performs  $\geq 25$  total mitral valve surgical procedures for severe MR per year of which at least 10 must be mitral valve repairs;
- An interventional cardiology program that performs  $\geq 1000$  catheterizations per year, including  $\geq 400$  Percutaneous Coronary Interventions (PCIs) per year, with acceptable outcomes for conventional procedures compared to National Cardiovascular Data Registry (NCDR) benchmarks;
- The heart team must include:
  1. An interventional cardiologist(s) who:
    - Performs  $\geq 50$  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

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- 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.
- All cases must be submitted to a single national database;
  - Ongoing continuing medical education (or the nursing/technologist equivalent) of 10 hours per year of relevant material; and
  - The cardiothoracic surgeon(s) must be board-certified in thoracic surgery or similar foreign equivalent.
  - 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.

The heart team and hospital must be 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. For complete details on the outcomes that must be tracked by the registry and the data that must be provided to the registry, see the CR9002 NCD transmittal. The Web address for that transmittal is in the "Additional Information" section at the end of this article.

## Coding Requirements/Claims Processing Requirements

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### **Coding Requirements for TMVR for MR Claims Furnished on or After August 7, 2014**

The Current Procedural Terminology (CPT) Codes for TMVR for MR Claims are:

- 0343T - Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis. (Note: 0343T will be replaced by CPT code 33418 effective January 1, 2015.)
- 0344T - 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). (Note: 0344T will be replaced by CPT code 33419 effective January 1, 2015.)

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- 0345T - Transcatheter mitral valve repair percutaneous approach via the coronary sinus
- 33418 - Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis. (Note: CPT code 33418 is effective January 1, 2015.)
- 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.) (Note: CPT code 33419 is effective January 1, 2015.)

### **ICD-9/ICD-10 Codes for TMVR for MR Claims**

The ICD-9 (and upon ICD-10 implementation)/ ICD-10 codes are:

- ICD-9 Procedure Code - 35.97 - Percutaneous mitral valve repair with implant - and ICD-10 procedure code is 02UG3JZ – Supplement mitral valve with synthetic substitute, percutaneous approach and
- ICD-9 Diagnosis Code for TMVR for MR Claims is - 424.0 – Mitral valve disorder and ICD-10 diagnosis codes are I34.0 – Nonrheumatic mitral (valve) insufficiency or I34.8 – Other nonrheumatic mitral valve disorders.

### **Professional Claims Place of Service (POS) Codes for TMVR for MR Claims**

Effective for claims with dates of service on and after August 7, 2014, place of service (POS) code 21 is valid for use for TMVR for MR services. All other POS codes will be denied. MACs will supply the following messages when MACs denying TMVR for MR claims for invalid POS:

- Claim Adjustment Reason Code (CARC) 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- Group Code CO (Contractual Obligation) assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed Advance Beneficiary Notice (ABN) is on file.)

### **Professional Claims Modifiers for TMVR for MR Claims**

Effective for claims with dates of service on or after August 7, 2014, MACs will pay claim lines for TMVR for MR billed with CPT codes 0343T, 0344T, and 0345T in a clinical trial when billed with modifier -Q0. (Effective January 1, 2015, CPT codes 33418 and 33419 replace CPT codes 0343T and 0344T, respectively.) TMVR for MR claim lines in a clinical trial billed without modifier -Q0 will be returned as unprocessable. MACs will supply the following messages when returning TMVR for MR claim lines in a clinical trial billed without modifier -Q0 as unprocessable:

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- CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- RARC N517: “Resubmit a new claim with the requested information.”
- Group Code: CO

### **Professional Clinical Trial Diagnostic Coding for TMVR for MR Claims**

Effective for claims with dates of service on or after August 7, 2014, MACs will pay claim lines for TMVR for MR billed with CPT codes 0343T, 0344T, and 0345T in a clinical trial when billed with ICD-9 diagnosis code 424.0 (ICD-10 I34.0 or I34.8) and secondary ICD-9 diagnosis code V70.7 (ICD-10=Z00.6). (Effective January 1, 2015, CPT codes 33418 and 33419 replace CPT codes 0343T and 0344T, respectively.) TMVR for MR claim lines in a clinical trial billed without ICD-9 diagnosis code 424.0 (ICD-10 I34.0 or I34.8) and secondary ICD-9 diagnosis code V70.7 (ICD-10=Z00.6) will be denied.

MACs will supply the following messages when denying TMVR for MR claim lines in a clinical trial billed without secondary ICD-9 diagnosis code V70.7(ICD-10=Z00.6) as unprocessable:

- CARC 50: “These are non-covered services because this is not deemed a “medical necessity” by the payer.”
- RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.”
- Group Code: CO

### **Mandatory National Clinical Trial (NCT) Number for TMVR for MR Claims**

Effective for claims with dates of service on or after August 7, 2014, contractors shall pay TMVR for MR claim lines billed with CPT codes 0343T, 0344T, and 0345T in a clinical trial only when billed with an 8-digit National Clinical Trial (NCT) number. (Effective January 1, 2015, CPT codes 33418 and 33419 replace CPT codes 0343T and 0344T, respectively.) MACs shall accept the numeric, 8-digit NCT number preceded by the two alpha characters of “CT” when placed in Field 19 of paper Form CMS-1500, or when entered WITHOUT the “CT” prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4). **NOTE:** The “CT” prefix is required on a paper claim, but it is not required on an electronic claim. TMVR for MR claim lines in a clinical trial billed without an 8-digit NCT number shall be returned as unprocessable. MACs will supply the following messages when returning TMVR for MR claim lines as unprocessable when billed without an 8-digit NCT number:

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- CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)”
- RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”
- Group Code: CO

### **Claims Processing Requirements for TMVR for MR on Inpatient Hospital Claims**

Inpatient hospitals shall bill for TMVR for MR on a 11X Type of Bill (TOB) effective for discharges on or after August 7, 2014. In addition to the ICD-9/10 procedure and diagnosis codes mentioned above, inpatient hospital discharges for TMVR for MR shall be covered when billed with the following clinical trial coding:

- Secondary ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6;
- Condition Code 30; and
- An 8-digit NCT Number assigned by the National Library of Medicine (NLM) and displayed at <https://clinicaltrials.gov/> on the Internet.

Inpatient hospital discharges for TMVR for MR will be rejected when billed without the ICD-9/10 diagnosis and procedure codes and clinical trial coding mentioned above. Claims that do not include these required codes shall be rejected with the following messages:

- CARC: 50 - “These are non-covered services because this is not deemed a “medical necessity” by the payer.”
- RARC N386 - “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.”
- Group Code - Contractual Obligation (CO)

### **Additional Information**

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The official instruction, CR9002, issued to your MAC regarding this change consists of two transmittals. The first updates the “Medicare Claims Processing Manual” and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3241CP.pdf> on the CMS website. The second updates the NCD Manual and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R178NCD.pdf> on the CMS website.

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If you have any questions, please contact your MAC at their toll-free number, which is available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

**Seasonal Flu Vaccinations** - Generally, Medicare Part B covers one flu vaccination and its administration per flu season for beneficiaries without co-pay or deductible. Now is the perfect time to vaccinate beneficiaries. Health care providers are encouraged to get a flu vaccine to help protect themselves from the flu and to keep from spreading it to their family, co-workers, and patients. Note: The flu vaccine is not a Part D-covered drug. For more information on coverage and billing of the influenza vaccine and its administration, please visit [MLN Matters® Article MM8890](#), “Influenza Vaccine Payment Allowances - Annual Update for 2014-2015 Season” and [MLN Matters® Article SE1431](#), “2014-2015 Influenza (Flu) Resources for Health Care Professionals.”

While some providers may offer flu vaccines, those that don’t can help their patients locate flu vaccines within their local community. The [HealthMap Vaccine Finder](#) is a free online service where users can search for locations offering flu and other adult vaccines. If you provide vaccination services and would like to be included in the HealthMap Vaccine Finder database, [register](#) for an account to submit your information in the database. Also, visit the CDC [Influenza \(Flu\)](#) web page for the latest information on flu including the CDC 2014-2015 recommendations for the prevention and control of influenza.

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