CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 178	**Date: December 5, 2014**
	Change Request 9002

NOTE: This Transmittal is no longer sensitive and is being re-communicated December 16, 2014 The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors payment shall be allowed for Transcatheter Mitral Valve Repair for (TMVR) under Coverage with Evidence Development.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: August 7, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2015

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	1/20.33/Transcatheter Mitral Valve Repair (TMVR)

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the

current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 178	Date: December 5, 2104	Change Request: 9002

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

EFFECTIVE DATE: August 7, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2015

I. GENERAL INFORMATION

A. Background: Transcatheter Mitral Valve Repair (TMVR) is a new technology for use in treating mitral regurgitation (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, in turn causing enlargement of the left ventricle and potential heart failure. Abbott's MitraClip, the only 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 lab or hybrid operating room/ cardiac catherterization lab 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.

B. Policy: On August 7, 2014 the Centers for Medicare and Medicaid services (CMS) issued a National Coverage Determination covering TMVR under Coverage with Evidence Development when the treatment is furnished for the treatment of mitral regurgitation and according to an FDA approved indication with an FDA-approved device, CED requires that each patient be entered into a qualified national registry. In addition, prior to receiving TMVR, face-to-face examinations of the patients are required by a cardiac surgeon and a cardiologist experienced in mitral valve surgery to evaluate the patient's suitability for TMVR. The NCD lists the criteria for the physician operators and hospitals that must be met prior to beginning a TMVR program and after a TMVR program is established.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
9002 - 03.1	Effective for claims with dates of service on or after August 7, 2014, contractors shall allow	X	X			X	X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	payment for TMVR for MR under CED only as outlined in Pub 100-03, chapter 1, section 20.33, of the NCD Manual and chapter 32, section 340, Medicare Claims Processing Manual, Pub.100-04.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9002 - 03.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Roya Lotfi, 410-786-4072 or roya.lotfi@cms.hhs.gov (Coverage) , Cami DiGiacomo, 410-786-5888 or cami.digiacomo@cms.hhs.gov (Institutional Claims Processing) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims Processing) , Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

20.33 - Transcatheter Mitral Valve Repair (TMVR)

(Rev. 178, Issued: 12-05-14, Effective: 08-07-14, Implementation: 04-06-15)

A. General

Transcatheter mitral valve repair (TMVR) is used in the treatment of mitral regurgitation. A TMVR device involves clipping together a portion of the mitral valve leaflets as treatment for reducing mitral regurgitation (MR); currently, Abbott Vascular's MitraClip® is the only one with Food and Drug Administration (FDA) approval.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers TMVR for 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).

The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):

- *When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?*

- *How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?*

- *What is the long-term (≥5 year) durability of the device?*
- *What are the long-term (≥5 year) outcomes and adverse events?*
- *How do the demographics of registry patients compare to the pivotal studies?*

Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

B. TMVR for MR uses that are not expressly listed as an FDA-approved indication when performed within an FDA-approved randomized controlled trial that fulfills all of the following:

1. TMVR must be performed by an interventional cardiologist or a cardiac surgeon. Interventional cardiologist(s) and cardiothoracic surgeon(s) may jointly participate in the intra-operative technical aspects of TMVR as appropriate.

2. As a fully-described, written part of its protocol, the clinical research trial must critically evaluate the following questions at 12 months or longer follow-up:

- *What is the rate of all-cause mortality in the group randomized to TMVR compared to the patients randomized to control (surgical repair, optimal medical therapy, or other specified control group)?*

- *What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the group randomized to TMVR compared to the patients randomized to control (surgical repair or other specified control group)?*

- *What is the rate of severe MR in the group randomized to TMVR compared to the patients randomized to control (surgical repair or other specified control group)?*

3. The randomized controlled trial must address all of the following questions at one year post- procedure:

- *What is the incidence of stroke?*

- *What is the incidence of TIAs?*

- *What is the incidence of major vascular events?*

- *What is the incidence of renal complications?*

- *What is the incidence of worsening MR?*

- *What is the patient's post-TMVR QoL?*

- *What is the patient's post-TMVR functional capacity?*

C. The CMS-approved clinical trials and registries must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity.

h. The research study has a written protocol that clearly addresses, or incorporates by reference; the standards listed as Medicare coverage requirements.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the AHRQ Registry of Patient Registries (RoPR).

k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).

l. *The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the*

recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: TMVR CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. Nationally Non-Covered Indications

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.

D. Other

NA

(This NCD last reviewed August 2014.)