

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 147</b>	<b>Date: September 24, 2012</b>
	<b>Change Request 7897</b>

**NOTE: Transmittal 145, dated August 3, 2012, is being rescinded and replaced by Transmittal 147, dated September 24, 2012, to include revisions to language in the “Summary of Changes” and clarification to the “Policy Section” of the business requirements for the Pub 100-03 and Pub 100-04 documents. All other information remains the same.**

**SUBJECT: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)**

**I. SUMMARY OF CHANGES:** On May 1, 2012, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering TAVR under Coverage with Evidence Development (CED). When the procedure is furnished for the treatment of symptomatic aortic stenosis and according to an FDA-approved indication for use with an approved device, CED requires that each patient be entered into a qualified national registry or participate in a qualifying clinical study.

**EFFECTIVE DATE: May 1, 2012**

**IMPLEMENTATION DATE: January 7, 2013**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N	1/20.32/Transcatheter Aortic Valve Replacement (TAVR)

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

**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**

*\*Unless otherwise specified, the effective date is the date of service.*

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 147	Date: September 24, 2012	Change Request: 7897
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**NOTE: Transmittal 145, dated August 3, 2012, is being rescinded and replaced by Transmittal 147, dated September 24, 2012, to include revisions to language in the “Summary of Changes” and clarification to the “Policy Section” of the business requirements for the Pub 100-03 and Pub 100-04 documents. All other information remains the same.**

**SUBJECT: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)**

**Effective Date:** May 1, 2012

**Implementation Date:** January 7, 2013

## **I. GENERAL INFORMATION**

**A. Background:** Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is a new technology for use in treating aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the native aortic valve. The procedure is performed in a cardiac catheterization lab or a hybrid operating room/cardiac catheterization lab with advanced quality imaging and with the ability to safely accommodate complicated cases that may require conversion to an open surgical procedure. The interventional cardiologist and cardiac surgeon jointly participate in the intra-operative technical aspects of TAVR.

**B. Policy:** On May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering TAVR under Coverage with Evidence Development (CED). When the procedure is furnished for the treatment of symptomatic aortic stenosis and according to an FDA-approved indication for use with an approved device, CED requires that each patient be entered into a qualified national registry. In addition, prior to receiving TAVR, face-to-face examinations of the patient are required by two cardiac surgeons to evaluate the patient’s suitability for open aortic valve replacement (AVR). The NCD lists criteria for the physician operators and hospitals that must be met prior to beginning a TAVR program and after a TAVR program is established.

For indications that are not approved by the FDA, patients must be enrolled in qualifying clinical studies. The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. Approved studies will be posted on the CMS web site at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html>. The process for submitting a clinical research study to Medicare is outlined in the NCD.

TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

## II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M M A C	F I  M A C	C A R I E R	R H H I  S	Shared-System Maintainers				OTHER
					F I S S	M I S S	V M S	C M S F			
7897-03.1	Effective for claims with dates of service on and after May 1, 2012, contractors shall cover TAVR under Coverage with Evidence Development (CED) when the procedure is furnished for the treatment of symptomatic aortic stenosis and according to an FDA approved indication for use with an approved device, in addition to the coverage criteria outlined in Pub 100-03, chapter 1, section 20.32 of the NCD Manual and chapter 32, section 290, Medicare Claims Processing Manual.	X		X	X		X				

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M M A C	F I  M A C	C A R I E R	R H H I  S	Shared-System Maintainers				OTHER
					F I S S	M I S S	V M S	C M S F			
7897-03.2	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> 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 site and include information about it in a listserv message within one week of the	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
		M A C	M A C				I S S	M S S	V M S	C W F	
	availability of the provider education article. In addition, the provider education article shall be included in your 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.										

**IV. SUPPORTING INFORMATION**

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: For all other recommendations and supporting information, use this space: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):**

**Pre-Implementation Contact(s):** Coverage: JoAnna Baldwin, 410-786-7205, [Joanna.Baldwin@cms.hhs.gov](mailto:Joanna.Baldwin@cms.hhs.gov), Wanda Belle, 410-786-7491, [wanda.belle@cms.hhs.gov](mailto:wanda.belle@cms.hhs.gov), Patti Brocato-Simons, 410-786-0261, [patti.brocatosimons@cms.hhs.gov](mailto:patti.brocatosimons@cms.hhs.gov); Practitioner Claims Processing: Cynthia Thomas, (410) 786-8169, [cynthia.thomas2@cms.hhs.gov](mailto:cynthia.thomas2@cms.hhs.gov), Chanelle Jones, (410) 786-9668, [chanelle.jones@cms.hhs.gov](mailto:chanelle.jones@cms.hhs.gov); Institutional Claims Processing: Sarah-Shirey-Losso, 410-786-0187, [sarah.shirey-losso@cms.hhs.gov](mailto:sarah.shirey-losso@cms.hhs.gov), Shauntari Cheely, (410) 786-1818, [Shauntari.cheely@cms.hhs.gov](mailto:Shauntari.cheely@cms.hhs.gov),

**Post-Implementation Contact(s):**

Contact your Contracting Officer’s Representative (COR) or Contractor Manager, as applicable.

**VI. FUNDING**

**Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers, use only one of the following statements:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**Section B: *For Medicare Administrative Contractors (MACs), include the following statement:***

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.

**20.32 – Transcatheter Aortic Valve Replacement (TAVR)**  
**(Rev. 147, Issued: 09-24-12, Effective: 05-01-12, Implementation: 01-07-13)**

**A. General**

*Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.*

**B. Nationally Covered Indications**

*The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:*

- A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met*
  - 1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.*
  - 2. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.*
  - 3. The patient (preoperatively and postoperatively) 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.*

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

- a. On-site heart valve surgery program,*
- b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,*
- c. Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),*
- 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. Appropriate volume requirements per the applicable qualifications below.*

*There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.*

*Qualifications to begin a TAVR program for hospitals without TAVR experience:*

*The hospital program must have the following:*

- a.  $\geq 50$  total AVRs in the previous year prior to TAVR, including  $\geq 10$  high-risk patients, and;*
- b.  $\geq 2$  physicians with cardiac surgery privileges, and;*
- c.  $\geq 1000$  catheterizations per year, including  $\geq 400$  percutaneous coronary interventions (PCIs) per year.*

*Qualifications to begin a TAVR program for heart teams without TAVR experience:*

*The heart team must include:*

- a. Cardiovascular surgeon with:
  - i.  $\geq 100$  career AVRs including 10 high-risk patients; or,*
  - ii.  $\geq 25$  AVRs in one year; or,*
  - iii.  $\geq 50$  AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and,**
- b. Interventional cardiologist with:
  - i. Professional experience with 100 structural heart disease procedures lifetime; or,*
  - ii. 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures; and,**
- .c- Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and,*
- d. Device-specific training as required by the manufacturer.*

*Qualifications for hospital programs with TAVR experience:*

*The hospital program must maintain the following:*

- a.  $\geq 20$  AVRs per year or  $\geq 40$  AVRs every 2 years; and,*
- b.  $\geq 2$  physicians with cardiac surgery privileges; and,*
- c.  $\geq 1000$  catheterizations per year, including  $\geq 400$  percutaneous coronary interventions (PCIs) per year.*

*Qualifications for heart teams with TAVR experience:*

*The heart team must include:*

- a. cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:
  - i.  $\geq 20$  TAVR procedures in the prior year, or,**



- ii.  $\geq 40$  TAVR procedures in the prior 2 years; and,
- b. Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.

4. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR 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 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. Stroke;
- ii. All cause mortality;
- iii. Transient Ischemic Attacks (TIAs);
- iv. Major vascular events;
- v. Acute kidney injury;
- vi. Repeat aortic valve procedures;
- vii. 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 ( $\geq 5$  year) durability of the device?
- What are the long term ( $\geq 5$  year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of 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. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following.

1. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR

*(minimum of 1 year), but must also address at least one of the following questions:*

- *What is the incidence of stroke?*
  - *What is the rate of all cause mortality?*
  - *What is the incidence of transient ischemic attacks (TIAs)?*
  - *What is the incidence of major vascular events?*
  - *What is the incidence of acute kidney injury?*
  - *What is the incidence of repeat aortic valve procedures?*
3. *The clinical study 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 the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56. In particular, the informed consent includes a straightforward explanation of the reported increased risks of stroke and vascular complications that have been published for TAVR.*
  - g. *All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).*
  - 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 study is registered on the [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) website by the principal sponsor/investigator prior to the enrollment of the first study subject.*
  - k. *The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The*

*results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.*

- 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.*

*4. 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: TAVR CED  
Centers for Medicare & Medicaid Services (CMS)  
7500 Security Blvd., Mail Stop S3-02-01  
Baltimore, MD 21244-1850*

**C. *Nationally Non-Covered Indications***

*TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.*

**D. *Other***

*NA*

*(This NCD last reviewed May 2012.)*