

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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MLN Matters® Number: MM7897

Related Change Request (CR) #: CR 7897

Related CR Release Date: September 24, 2012

Effective Date: May 1, 2012

Related CR Transmittal #: R2552CP and R147NCD

Implementation Date: January 7, 2013

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

Note: This article was revised on January 4, 2014, to add a reference to MLN Matters® article MM8537 (<http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8537.pdf>) to alert providers that, effective January 1, 2014, the remaining temporary CPT code for this procedure (0318T) is replaced with CPT code 33366. More detailed billing instructions are also provided. All other information is the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians and hospitals who provide Transcatheter Aortic Valve Replacement (TAVR) services to Medicare beneficiaries.

Provider Action Needed



STOP – Impact to You

Effective for claims with dates of service on and after May 1, 2012, Medicare Carriers, Fiscal Intermediaries (FIs), and Medicare Administrative Contractors (A/B MACs) will reimburse for Transcatheter Aortic Valve Replacement (TAVR) under Coverage with Evidence Development (CED).

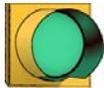
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CAUTION – What You Need to Know

Change Request (CR) 7897, from which this article is taken, announces that on May 1, 2012, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering TAVR under CED and CR7897 details requirements that must be met when claims are submitted to Medicare for these services.



GO – What You Need to Do

You should make sure that your billing staffs are aware of this decision and its requirements which are summarized in the Background section below.

Background

Transcatheter Aortic Valve Replacement (TAVR - also known as TAVI or Transcatheter Aortic Valve Implantation) is a new technology for use in treating certain patients with aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the native aortic valve.

CR7879, from which this article is taken, announces that 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) and only when specific requirements are met.

CED Coverage Conditions with Registry Participation

CMS covers TAVR for the treatment of symptomatic aortic valve stenosis under CED with the following conditions:

1. It is furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:
 - a. It is furnished with a complete aortic valve and implantation system that has received FDA Premarket Approval (PMA) for that system's FDA approved indication;
 - b. 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 this rationale is available to the heart team;
 - c. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals that embodies collaboration and dedication across medical specialties to offer optimal patient-centered care;
 - d. It is furnished in a hospital with the appropriate infrastructure that includes (but is not limited to):
 - On-site heart valve surgery program;

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- Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging;
 - Non-invasive imaging such as echocardiography, vascular ultrasound, Computed Tomography (CT) and Magnetic Resonance (MR);
 - 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; and
 - Appropriate volume requirements per the applicable qualifications (specifically, for hospitals without TAVR experience and for those with experience performing the procedure), which follow.
2. Required qualifications for the hospitals and heart teams performing the procedure.

Hospitals without TAVR experience must have the following qualifications to begin a TAVR program:

- a. ≥ 50 total AVRs in the previous year prior to TAVR, including ≥ 10 high-risk patients;
- b. \geq Two physicians with cardiac surgery privileges; and
- c. ≥ 1000 catheterizations per year, including ≥ 400 Percutaneous Coronary Interventions (PCIs) per year.

Heart Teams without TAVR experience must include the following to begin a TAVR program:

- a. A cardiovascular surgeon with: 1) ≥ 100 career AVRs including 10 high-risk patients; or, 2) ≥ 25 AVRs in one year; or, 3) ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and,
- b. An interventional cardiologist with: 1) Professional experience with 100 structural heart disease procedures lifetime; or, 2) 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; as well as
- 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.

Hospital programs with TAVR experience must have the following qualifications:

- a. Maintain ≥ 2 physicians with cardiac surgery privileges;
- b. Perform ≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and
- c. Perform ≥ 1000 catheterizations per year, including ≥ 400 Percutaneous Coronary Interventions (PCIs) per year.

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Heart teams with TAVR experience must have the following qualifications:

- a. Include a cardiovascular surgeon and an interventional cardiologist whose combined experience maintains: 1) ≥ 20 TAVR procedures in the prior year, or 2) ≥ 40 TAVR procedures in the prior 2 years;
- b. Include additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and
- c. The interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

In addition, the heart team and hospital must be participating in a prospective, national, audited registry. The complete list of requirements for a qualifying registry can be found in the NCD, which is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R147NCD.pdf> on the CMS website. To date, CMS has approved one registry, the Transcatheter Valve Therapy Registry, operated by the Society of Thoracic Surgeons and the American College of Cardiology.

CED Coverage Conditions with Clinical Studies

For indications that are not approved by the FDA, CMS covers TAVR under CED when patients are enrolled in qualifying clinical studies. The clinical study requirements are available in the NCD, which is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R147NCD.pdf> on the CMS website. Approved studies are listed at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html> on the CMS website.

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

Coding Requirements -Professional Claims

For TAVR services furnished on or after May 1, 2012, you should bill with the appropriate temporary level III Current Procedural Terminology (CPT) code:

- 0256T: Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach;
- 0257T: Implantation of catheter-delivered prosthetic aortic heart valve; open thoracic approach (eg, transapical, transventricular);
- 0258T: Transthoracic cardiac exposure (i.e. sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; without cardiopulmonary bypass; and
- 0259T: Transthoracic cardiac exposure (i.e. sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement; with cardiopulmonary bypass.

Beginning January 1, 2013, CMS anticipates permanent CPT level 1 codes will replace the above 4 codes for processing TAVR claims, and will issue instructions for the permanent CPT level 1 codes in a future CR.

You should be aware that, on or after May 1, 2012, your carrier or A/B MAC will only reimburse your professional claims for TAVR services (for CPT codes 0256T, 0257T, 0258T, and 0259T) when used

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with Place of Service (POS) code 21 (Inpatient Hospital). They will deny all other POS codes. Should they deny your claim because of an incorrect POS, they will use the following messages:

- 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;"
- Remittance advice remark code (RARC) N428: "Not covered when performed in this place of service;" and
- Group Code: Contractual Obligation (CO).

Similarly, Medicare will only pay claim lines with these TAVR CPT codes when billed with modifier 62 (two surgeons/co-surgeons). They will return all others as unprocessable. Should they return such claims, they will use:

- 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 N29: "Missing documentation/orders/notes/summary/report/chart;" and
- Group Code: Contractual Obligation (CO).

Medicare will only pay claim lines for these codes in a clinical trial when billed with modifier Q0 (zero). For TAVR services, use of modifier Q0 signifies CED participation (qualified registry or qualified clinical study). They will return such claims billed without modifier Q0 as unprocessable using:

- 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 N29: "Missing documentation/orders/notes/summary/report/chart;" and
- Group Code: Contractual Obligation (CO).

Medicare will only pay claims for these codes in a clinical trial when billed with International Classification of Diseases, Ninth Revision Clinical Modification (ICD-9-CM) secondary diagnosis code V70.7 (routine general medical examination at a health care facility) (ICD-10 = Z00.6 -- encounter for examination for normal comparison and control in clinical research program). For TAVR services, use of V70.7 signifies CED participation (qualified registry or qualified clinical study). They will return claim lines billed without secondary diagnosis code V70.7 as unprocessable, using:

- CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT);"
- RARC N29: "Missing documentation/orders/notes/summary/report/chart;" and
- Group Code Contractual Obligation (CO).

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Coding Requirements - Inpatient Hospital Claims

Hospitals should bill for TAVR services on an 11X Type of Bill (TOB), effective for discharges on or after May 1, 2012. Your FI or A/B MAC will reimburse such claims containing ICD-9 procedure codes 35.05 (Endovascular replacement of aortic valve) or 35.06 (Transapical replacement of aortic valve) only when billed with secondary diagnosis code V70.7 (Examination of participant in clinical trial) and condition code 30 (qualifying clinical trial). For TAVR services, use of the latter two codes signifies CED participation (qualified registry or qualified clinical study).

Claims from hospitals without those latter two codes will be rejected using:

- 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 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;" and
- Group Code: Contractual Obligation (CO).

The following are the ICD-10 procedure codes applicable for TAVR:

TAVR ICD-9 Procedure Codes	TAVR ICD-10 Procedure Codes
35.05	02RF37Z 02RF38Z 02RF3JZ 02RF3KZ
35.06	02RF37H 02RF38H 02RF3JH 02RF3KH

Additional Information

Note: This article was previously revised on July 6, 2013, to add a reference to MLN Matters® Article MM8255 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8255.pdf>) to alert providers who submit claims for Transcatheter Aortic Valve Replacement (TAVR) that beginning July 1, 2012, all claims for TAVR must carry the approved clinical trial number under which the procedure is performed.

CR7897 was issued to your Medicare contractor in two transmittals. The first transmittal modifies the "Medicare National Coverage Determinations Manual" and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R147NCD.pdf> on the CMS website. The second transmittal updates the "Medicare Claims Processing Manual" and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2552CP.pdf> on the CMS website.

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You may want to review MLN Matters® article MM8168 (<http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8168.pdf>), which updates CR7897 and clarifies the use of modifier 62 and the documentation requirements, surgical team criteria, and managed care plan claims processing instructions.

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

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