

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



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- ["The Basics of Medicare Enrollment for Physicians Who Infrequently Receive Medicare Reimbursement"](#), Fact Sheet, ICN 006881, downloadable

MLN Matters® Number: MM8168

Related Change Request (CR) #: CR 8168

Related CR Release Date: January 7, 2013

Effective Date: January 1, 2013

Related CR Transmittal #: R2628CP

Implementation Date: April 1, 2013 (except January 25, 2013 for claims sent to carriers/B MACs)

### **National Coverage Determination (NCD): Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification**

Note: This article was revised on August 31, 2015. For more information on this revision and other revisions, please refer to the "Document History" section in this article.

#### **Provider Types Affected**

This MLN Matters® Article is intended for physicians, providers and suppliers submitting claims to Medicare contractors (Fiscal Intermediaries (FIs), carriers and A/B Medicare Administrative Contractors (MAC)) for Transcatheter Aortic Valve Replacement (TAVR) services to Medicare beneficiaries.

#### **What You Need to Know**

Change Request (CR) 7897, issued September 24, 2012, implemented a new National Coverage Determination (NCD), TAVR, also known as Transcatheter Aortic Valve Implantation (TAVI), a new technology for use in treating aortic stenosis. CR 7897 provided billing/coding instructions that included codes expiring on December 31, 2012. CR8168 is an update to CR7897 that implements replacement codes for TAVR claims with dates of service on and after January 1, 2013. Those codes appear in the 2013

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Physician Fee Schedule.

CR 8168 also clarifies several policy-related issues regarding use of modifier 62 and the documentation requirements, surgical team criteria, and managed care plan claims processing instructions. Please make sure that your billing staffs are aware of these updates.

## Background

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TAVR, or TAVI, is a new technology for use in treating aortic stenosis. A bioprosthetic valve is inserted intravascularly 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 cardiothoracic surgeon jointly participate in the intra-operative technical aspects of TAVR.

On May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a NCD covering TAVR under Coverage with Evidence Development (CED). When the procedure is furnished for the treatment of symptomatic aortic stenosis and according to a Food and Drug Administration (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.

According to CR 7897, issued September 24, 2012, TAVR claims with dates of service on and after May 1, 2012, through December 31, 2012, are billed with temporary category III Current Procedural Terminology (CPT) codes 0256T (Implantation of catheter-delivered prosthetic aortic heart valve: endovascular approach); 0257T (Implantation of catheter-delivered prosthetic aortic heart valve: open thoracic approach (for example, transapical, transventricular)); 0258T (Transthoracic cardiac exposure (that is, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement, without cardiopulmonary bypass); and 0259T (Transthoracic cardiac exposure (that is, sternotomy, thoracotomy, subxiphoid) for catheter-delivered aortic valve replacement, with cardiopulmonary bypass). These codes are contractor-priced.

### ***Billing for TAVR on and after January 1, 2013***

TAVR claims with dates of service on and after January 1, 2013 must be billed with five permanent CPT category 1 codes and one temporary category 3 code. These six codes will replace the four temporary codes that expired on December 31, 2012. All other Medicare claims processing instructions as they relate to TAVR and these new codes have been updated accordingly.

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Thus, effective for dates of service on and after January 1, 2013, Medicare recognizes the following codes when billing for TAVR:

- 33361 - Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach;
- 33362 - Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach;
- 33363 - Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach;
- 33364 - Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach;
- 33365 - Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (for example, median sternotomy, mediastinotomy); and
- 0318T Replace aortic valve thoracic.

In addition to these codes, the claim must have a Place of Service (POS) code of 21 (inpatient Hospital) or the claim lines will be denied with a Claim Adjustment Reason Code (CARC) of 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.), a Remittance Advice Remarks Code (RARC) of N428 (Not covered when performed in this place of service.) and a Group Code of CO (Contractual Obligation).

Also, the claim lines for these procedure codes on professional clinical trial claims must have the modifier Q0 (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) or the lines will be returned with a CARC of 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.), a RARC of N29 (Missing documentation/orders/notes/summary/report/chart.), and the Group Code of CO.

Similarly, professional claims with one of the above procedure codes must have modifier 62 also or the claim line will be returned with a CARC of 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.), a RARC of N29 (Missing documentation/orders/notes/summary/report/chart.), and the Group Code of CO.

Finally, the clinical trial claim line must contain the secondary diagnosis code of V70.7 (ICD-10 of Z00.6) or it will be returned with a CARC of 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

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Remark Code that is not an ALERT.)), a RARC of M76 (Missing/incomplete/invalid diagnosis or condition.), and the Group Code of CO.

For claims processed prior to implementation of these changes, your Medicare contractor will adjust such claims but only if you bring such claims to the contractor's attention.

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> on the CMS website. The process for submitting a clinical research study to Medicare is outlined in the NCD.

The NCD requires an interventional cardiologist and a cardiothoracic surgeon to jointly participate in the intraoperative technical aspects of TAVR as specified in section 20.32 of the “NCD Manual”. All TAVR codes must be billed with modifier 62 (two surgeons) with the exception of the three new add-on codes 33367, 33368, and 33369, effective January 1, 2013.

For further information, see the MLN Matters® Article related to CR 7897. That article is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7897.pdf> on the CMS website.

**Note:** When a Medicare Advantage (MA) plan participant receives TAVR services, the MA plans are responsible for payment. Medicare coverage for TAVR is not under section 310.1 of the NCD Manual (Routine Costs in Qualifying Clinical Trials) and it is in these trials that the fee-for-service (FFS) system is responsible for payment.

## Additional Information

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The official instruction, CR 8168, issued to your FI, carrier and A/B MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2628CP.pdf> on the CMS website.

If you have any questions, please contact your FI, carrier 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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## Document History

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Date	Description
August 27, 2015	The article was revised to add a reference link to SE1515 ( <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1515.pdf">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1515.pdf</a> ) to remind providers of the hospital volume requirements for TAVR programs.
January 4, 2014	The article added a reference link to MM8537 ( <a href="http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8537.pdf">http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8537.pdf</a> ) 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.
July 6, 2013	The article added a reference link to MM8255 ( <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8255.pdf">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8255.pdf</a> ) that alerts providers, who submit claims for Transcatheter Aortic Valve replacement (TAVR), that beginning July 1, 2012, all claims for TAVR must carry the approved clinical trail number under which the procedure is performed.
January 15, 2013	This article was changed to correct modifier of 62 in the third full paragraph of page 3.

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