

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



CMS is accepting Notices of Intent to Apply for the Medicare Shared Savings Program, Program Start Date January 1, 2014 – NOI Due by May 31. If you are interested in applying for participation for the January 1, 2014 program start date of the Medicare Shared Savings Program, please submit a Notice of Intent to Apply (NOI) by May 31, 2013. For more information, visit the [Shared Savings Program Application](#) web page. To learn more about the application process, [register](#) to attend upcoming National Provider Calls on June 20 and July 18.

MLN Matters® Number: MM8255

Related Change Request (CR) #: CR 8255

Related CR Release Date: July 11, 2013

Effective Date: July 1, 2013

Related CR Transmittal #: R2737CP

Implementation Date: October 7, 2013

National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) – Implementation of Mandatory Reporting of Clinical Trial Number

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, other providers, and suppliers who submit claims to Medicare contractors (Fiscal Intermediaries (FIs), carriers, and A/B Medicare Administrative Contractors (A/B MACs)) for Transcatheter Aortic Valve Replacement (TAVR) services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 8255 is being issued to require that claims for TAVR carry an approved clinical trial number, effective for claims processed on or after July 1, 2013. Given that TAVR is covered only under Coverage with Evidence Development (CED), the Centers

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for Medicare & Medicaid Services (CMS) has ensured that the approved clinical trials and approved registry have obtained valid numbers from <http://www.clinicaltrials.gov> and that those numbers are maintained at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html> on the CMS website. See the Background and Additional Information Sections of this article for further details regarding these changes. Please make sure that your billing staffs are aware of these changes.

Background

On May 1, 2012, CMS issued a National Coverage Determination (NCD) covering TAVR with CED. The TAVR NCD is available at <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355> on the CMS website.

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.

CR8255 requires that claims for TAVR carry an approved clinical trial number. Specific claims processing instructions are as follows:

- For professional claims processed on or after July 1, 2013, Medicare expects this numeric, 8-digit clinical trial (CT) registry number to be preceded by the alpha characters of "CT" in Field 19 of paper Form CMS-1500 claims or entered similarly **BUT WITHOUT THE "CT" prefix in the electronic 837P in Loop 2300 REF01 (REF01=P4).**
- Professional claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365, and 0318T must have the CT registry number, a Q0 modifier, and a secondary diagnosis code of V70.7 (ICD-10=Z00.6). Such claims lines will be returned as unprocessable if the CT registry number, the modifier Q0, or the V70.7 (ICD-10=Z00.6) is not present.

Claims for TAVR submitted without the CT registry number will be returned as unprocessable with the following messages:

- Claims Adjustment Remarks Code (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.) ;
- Remittance Advice Remarks Code (RARC) MA50: Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services. ;

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- RARC MA130: Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information. ; and
- Group Code-Contractual Obligation (CO).

TAVR claims submitted without the Q0 modifier will be returned as unprocessable with the following messages:

- 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.;
- RARC MA130: Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information. and
- Group Code-Contractual Obligation (CO).

For claims processed on or after July 1, 2013, the claim lines for 0256T, 0257T, 0258T, 0259T, 33361, 33362, 33363, 33364, 33365 & 0318T will be returned as unprocessable when billed without secondary diagnosis code V70.7 (ICD-10=Z00.6) with the following messages:

- 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 M76: Missing incomplete/invalid diagnosis or condition.
- RARC MA130: Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information and
- Group Code-Contractual Obligation (CO).

Medicare also requires the CT registry number on hospital claims for TAVR for inpatient hospital discharges on or after July 1, 2013. Claims for TAVR for inpatient discharges on or after July 1, 2013, that do not have the registry number will be rejected. Medicare is ensuring the presence of the procedure codes and associated diagnosis and condition codes per CR7897/TR2552, issued September 24, 2012.

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Additional Information

The official instruction, CR 8255 issued to your Medicare contractor regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2737CP.pdf> on the CMS website.

For more information regarding the Medicare approved registry and the Medicare approved clinical trials which have been reviewed and determined to meet the requirements of coverage go to <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Transcatheter-Aortic-Valve-Replacement-TAVR-.html> on the CMS website.

You may also want to review two related TAVR articles MM8168 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8168.pdf>) and MM7897 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7897.pdf>) on the CMS website.

If you have any questions, please contact your Medicare contractor 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

Date	Description
August 27, 2015	The article was revised to add a reference link to SE1515 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1515.pdf) to remind providers of the hospital volume requirements for TAVR programs.
January 4, 2014	The article was revised reference link to 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 were also provided
July 12, 2013	The article was revised to reflect the revised CR8255 issued on July 11, 2013. The article has been updated to clarify on page 2 that the addition of "CT" with the registry number is only for paper claims. Also, Web addresses for the articles related to CRs 7897 and 8168 were added. The CR release date, transmittal number and the Web address for accessing CR8255 are revised. All other content remains the same.

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