NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)

MLN Matters Number: MM11660
Related CR Release Date: March 13, 2020
Effective Date: June 21, 2019
Related CR Transmittal Number: R4546CP and R217NCD
Implementation Date: June 12, 2020

PROVIDER TYPES AFFECTED

This MLN Matters Article is for physicians, providers and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 11660 informs MACs that effective June 21, 2019, the Centers for Medicare & Medicaid Services (CMS) will continue coverage of Transcatheter Aortic Valve Replacement (TAVR) under Coverage with Evidence Development (CED) when the procedure is provided for the treatment of symptomatic aortic valve stenosis and according to a Food & Drug Administration (FDA)-approved indication for use with an approved device, in addition to the coverage criteria outlined in the Medicare National Coverage Determinations (NCD) Manual (Pub. 100-03). CMS will also continue coverage of TAVR for uses that are not expressly listed as an FDA-approved indication in clinical studies that meet specific requirements and are approved by CMS.

These changes relate to Chapter 1, Part 1, Section 20.32 of the NCD Manual and Chapter 32, Section 290 of the Medicare Claims Processing Manual (Pub. 100-04). Both relevant sections are attached to CR 11660.

BACKGROUND

TAVR, also known as Transcatheter Aortic Valve Implantation (TAVI), is used to treat aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

On June 21, 2019, CMS issued an NCD to continue covering TAVR under CED. When the procedure is provided for the treatment of symptomatic aortic stenosis and according to an FDA-approved indication for use with an approved device, CED requires that each beneficiary be entered into a qualified national registry. 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 uses that are not expressly listed as an FDA-approved indication, beneficiaries must be enrolled in qualifying clinical studies. All clinical research study protocols must:

- Address pre-specified research questions
- Adhere to standards of scientific integrity
- Be reviewed and approved by CMS

Approved studies will be posted at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. The submission process for a clinical research study to Medicare is outlined in the NCD.

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

This reconsideration of TAVR makes changes to criteria for the heart team and the hospital, and to the trial outcomes and the registry questions/criteria. Other than messaging all current claims processing instructions remain.

The key messaging changes are as follows:

- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer report Remittance Advice Remark Code (RARC) N428 on remittances for claims denied for invalid place of service (POS).
- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer accept RARC N29 on remittances for claims billed without modifier -62 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will report Group Code – Contractual Obligation (CO) on remittances for claims billed without modifier -62 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer accept RARC N29 on remittances for claims billed without modifier –Q0 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will report Group Code – CO on remittances for claims billed without modifier –Q0 and returned as unprocessable.
- Effective for TAVR claims processed on and after January 2, 2020, MACs will no longer report Medicare Summary Notice (MSN) 16.77 on remittances for claims billed without ICD-10 diagnosis code Z00.6 and returned as unprocessable.

**ADDITIONAL INFORMATION**

The official instruction, CR 11660, was issued to your MAC regarding this change via two transmittals. The first updates the Medicare Claims Processing Manual at https://www.cms.gov/files/document/r4546cp.pdf. The second updates the NCD Manual and it is
If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Date of Change</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 24, 2020</td>
<td>Initial article released.</td>
</tr>
</tbody>
</table>

Disclaimer: Paid for by the Department of Health & Human Services. This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents. CPT only copyright 2019 American Medical Association. All rights reserved.

Copyright © 2013-2020, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816. You may also contact us at ub04@healthforum.com

The American Hospital Association (the “AHA”) has not reviewed, and is not responsible for, the completeness or accuracy of any information contained in this material, nor was the AHA or any of its affiliates, involved in the preparation of this material, or the analysis of information provided in the material. The views and/or positions presented in the material do not necessarily represent the views of the AHA. CMS and its products and services are not endorsed by the AHA or any of its affiliates.