

Compliance Today - November 2019 TAVR turbulence

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The STS/ACC TVT Registry TM has been approved by the Centers for Medicare & Medicaid Services (CMS) to meet the registry requirements outlined in the national coverage decisions for transcatheter aortic valve replacement (TAVR) [1] and transcatheter mitral valve repair (TMVR). This TVT Registry TM delivers insight into practice patterns and patient outcomes for transcatheter valve replacement and repair procedures, and will include all patients 18 years or over who undergo TAVR for severe aortic stenosis.

Facility billing for the TAVR, also known as transcatheter aortic valve implantation (TAVI), became nationally covered in 2012 under Coverage with Evidence Development (CED). This is extremely confusing for clinical trial billing and revenue cycle teams, and there are many coding fundamentals that should be followed, says Cynthie Lawson, BSBM, CHRC, CPC. In discussing the coding on these registries and trials, Ms. Lawson, a certified coder, said, "It is important to remember that billing instructions for TAVR are not the same as billing instructions for IDEs [Investigational Device Exemptions]. First, a site must know that they are an approved TAVR study location prior to submitting any claims." [3]

TAVR Registry Part A claims should include the ICD-10 TAVR procedure codes, secondary diagnosis ICD-10 code Z00.6, Condition Code 30 (qualifying clinical trial), valid 8-digit registry NCT number, revenue code 0278 (Medical/surgical supplies and devices – Other Transplant), along with the billed charge.

TAVR Registry Part B claims should include the appropriate CPT code for the TAVR procedure (33361–33365) with the Q0 modifier assigned, secondary diagnosis ICD-10 code Z00.6, and valid 8-digit registry NCT number.

Qualifying IDE study Part A claims should include the ICD-10 TAVR procedure codes, secondary diagnosis ICD-10 code Z00.6, Condition Code 30 (qualifying clinical trial), valid 8-digit clinical trial NCT number, revenue code 0624 (FDA investigational devices), and the IDE number in the description field, along with the billed charge.

Qualifying IDE study Part B claims should report the appropriate CPT code for the TAVR procedure (33361-33365) with the Qo modifier assigned, secondary diagnosis ICD-10 code Z00.6, and valid 8-digit clinical trial NCT number.

Sites should refer to CMS and their local Medicare Administrative Contractor's (MAC) directive for specific billing requirements for TAVR CED and TAVR clinical trials. Medicare coverage for TAVR does not fall under section 310.1 of the NCD Manual (Routine Costs in Qualifying Clinical Trials) but rather the device rules of a clinical trial. All patients should understand their financial responsibility during the consent process due to some payers denying claims for both the registry and IDE studies.

<u>1</u> CMS.gov, Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430N) https://go.cms.gov/20Wkyv8

2 CMS.gov, National Coverage Determination (NCD) for Transcatheter Mitral Valve Repair (TMVR) (20.33)

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https://go.cms.gov/2lVMhiw 3 From phone interview with Cynthie Lawson in July 2019.
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