

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



May is Mental Health Month. Medicare provides payment for several preventive services that can be used to help monitor your patients' mental health including:

- Screening for Depression in Adults
- Annual Wellness Visit (Providing Personalized Prevention Plan Services)
- Initial Preventive Physical Examination

[Read more](#) to learn about Medicare coverage of preventive services.

MLN Matters® Number: SE1515

Related Change Request (CR) #: N/A

Related CR Release Date: N/A

Effective Date: N/A

Related CR Transmittal #: N/A

Implementation Date: N/A

Transcatheter Aortic Valve Replacement (TAVR) Hospital Program Volume Requirements

Provider Types Affected

This MLN Matters® Special Edition article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors for TAVR services provided to Medicare beneficiaries.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) established Medicare coverage criteria for individual hospitals that want to perform Transcatheter Aortic Valve Replacement (TAVR). Before a TAVR procedure is eligible for Medicare coverage individual hospitals must meet the volume requirements specified in the TAVR national coverage determination (NCD). Hospitals that do not meet these volume requirements are not eligible for waivers or exceptions. This special edition article is being provided by CMS to remind providers of the hospital volume requirements for TAVR programs.

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Background

TAVR, also known as transcatheter aortic valve implantation (TAVI), is a 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.

Effective May 1, 2012, Medicare covers TAVR procedures under coverage with evidence development (CED) for the treatment of symptomatic aortic stenosis when:

- Furnished according to a Food and Drug Administration (FDA) approved indication; and
- Certain conditions are met including requirements for individual hospitals in which TAVR procedures are performed.

Hospital Volume Requirements

CMS established specific volume requirements pertaining to various procedures that hospitals with and without TAVR experience must meet. In order for a hospital to perform TAVR procedures in compliance with the NCD for TAVR ([NCD 20.32](#)) and be eligible for Medicare coverage, the individual hospital must meet these volume requirements.

The hospital TAVR program volume requirements are specific to each individual hospital site where TAVR procedures are performed, and they are as follows:

- 1. To begin a TAVR program, the hospital (without TAVR experience) must have:**
 - a. ≥ 50 total aortic valve replacements (AVRs) in the previous year prior to TAVR, including ≥ 10 high-risk patients; and
 - b. ≥ 2 physicians with cardiac surgery privileges; and
 - c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.
- 2. To continue a TAVR program, the hospital (with TAVR experience) must maintain:**
 - a. ≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and
 - b. ≥ 2 physicians with cardiac surgery privileges; and
 - c. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

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It is important to note that there are also requirements for heart team members and these volume requirements may include procedures performed at different facilities, but the hospital volume requirements are specific to the site where TAVR procedures are performed. **Hospitals that do not meet these volume requirements are not eligible for waivers or exceptions.**

In addition, hospital systems comprised of multiple individual sites (that may or may not be in close proximity to each other) may not combine procedural experiences at multiple sites to meet these volume requirements.

Additional Information

You can review the complete National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) which details all requirements that must be met for Medicare coverage at <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355> on the CMS website.

The Medicare approved TAVR registry and Medicare approved clinical trials which were reviewed and determined to meet the requirements of Medicare coverage are available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html> on the CMS website.

You can review the MLN Matters® Article MM8168 titled *National Coverage Determination (NCD): Transcatheter Aortic Valve Replacement (TAVR) Coding Update/Policy Clarification* at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8168.pdf> on the CMS website.

You can find the Medicare “National Coverage Determinations Manual” (Publication 100-03; Chapter 1, Part 1, Section 20.32 (Transcatheter Aortic Valve Replacement (TAVR))) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part1.pdf on the CMS website.

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