



Medicare Part C Medical Coverage Policy

Transcatheter Aortic Valve Replacement (TAVR)

Origination: June 18, 2014

Review Date: August 2, 2022

Next Review: August, 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE:

Transcatheter Aortic Valve Replacement (TAVR) also known as Transcatheter Aortic Valve Implantation (TAVI) is used to treat members with aortic stenosis. A bio prosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the native aortic valve.

DEFINITIONS:

Coverage with Evidence Development (CED): At times, The Centers for Medicare & Medicaid (CMS) issues a national coverage determination with data collection as a condition of coverage. The CED concept considers the item or service to be reasonable and necessary only while evidence is being developed regarding member's health outcomes in a clinical trial. CMS lists these clinical trials with CED at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>.

POLICY STATEMENT

The Plan covers TAVR under CED based on meeting CMS conditions set forth in the National Coverage Determination (NCD).

BENEFIT APPLICATION

Refer to the member's individual Evidence of Coverage (EOC) for the benefit determination. Coverage will be approved according to the EOC limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; **AND**
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Medical Coverage Policy: Transcatheter Aortic Valve Replacement (TAVR)

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the medical coverage policy manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE:

1. The indication for coverage is symptomatic aortic valve stenosis; **AND**
2. The device is FDA approved for symptomatic aortic stenosis; **AND**
3. Two cardiac surgeons have independently examined the patient face to face and evaluated the member's suitability for open aortic valve replacement and documented their rationale for the TAVR; **AND**
4. The hospital must be listed in the Transcatheter Valve Therapy (TVT) Registry: <https://www.ncdr.com/TVT/Home/Default.aspx> .

OR

5. Medicare may cover TAVR for uses that are not expressly listed as an FDA approved indication when performed within a Medicare qualified clinical trial; approved studies must be identified on the CMS website: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html>.

WHEN COVERAGE WILL NOT BE APPROVED

When the above criteria are not met.

TAVR is not covered in patients with existing comorbidities that are significant enough to inhibit the expected benefit from correction of the aortic stenosis.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee that it will be reimbursed.

Applicable codes: 33361; 33362; 33363; 33364; 33365; 33366

SPECIAL NOTES:

TAVR is performed at the inpatient level of care.

The TVT (Transcatheter Valve Therapy) Registry has been approved by CMS to meet the registry volume requirements outlined in the NCD for TAVR.

Medical Coverage Policy: Transcatheter Aortic Valve Replacement (TAVR)

References:

1. National Coverage Determination for Transcatheter Aortic Valve Replacement (TAVR)20.32; Viewed online at www.cms.gov; viewed on 8/2/2022.
2. MLN Matters; MM7897; Effective date May 1, 2012; Revised 01/07/2014; Viewed online at www.cms.gov on 8/2/2022
3. MLN Matters; MMSE1515 Transcatheter Aortic Valve Replacement (TAVR) Hospital Program Volume Requirements; Effective date: N/A; Viewed online at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1515.pdf>; viewed on 06/10/2015 (old reference). STS/ACC Transcatheter Valve Therapy (TVT) Registry; Viewed online at <https://www.ncdr.com/TVT/Home/Default.aspx>, viewed on 8/2/2022.

Policy Implementation/Update Information:

New Policy: 06/18/2014; new policy created for staff clarification and CMS guidance per the NCD.

Minor Revision: 03/18/15; moved item #7 up to #2 under section Indications For Coverage to remain consistent with TMVR policy.

Revision Date: 06/10/2015; under Indications For Coverage, added item #7 volume requirements for hospitals to be eligible to perform the TAVR procedure as outlined in the MLN and NCD for TAVR also added the link to identify registered hospitals that meet the requirements. Updated the link for CMS approved TAVR registry; updated reference section.

Revision Date: 06/18/2015; Under Special Notes, added the current list of North Carolina facilities approved through the Transcatheter Valve Therapy (TVT) registry meeting volume requirements.

Revision Date: 12/21/2016: Definition Section: Removed verbiage "CMS maintains a registry of facilities that have agreed to the clinical indications specified in the NCD." Indications for Coverage: Removed "Has to be done in an inpatient facility" Removed "Preauthorization by the Plan is required" Added "Medicare may cover TAVR for uses that are not expressly listed as an FDA approved indication when performed within a Medicare qualified clinical trial; approved studies must be identified on the CMS website: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html>." Special Notes added "TAVR is performed at the inpatient level of care"

Revision Date: 11/21/2018: Annual Review; No CMS Updates. Indications for Coverage; Removed #1 "The Medical Director will review all TAVR requests" per committee recommendation.

Revision Date: 8/4/2020; Annual Review. No CMS Updates. Minor Revisions Only.

Revision Date: 8/2/2022; Annual Review. No CMS updates. Minor revisions only.

Approval Dates:

Medical Coverage Policy Committee: August 17, 2022

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