Regence Oregon and Utah | Regence Idaho and select counties of Washington

**Medicare Advantage Policy Manual** **Policy ID:** M-SUR201

# *Transcatheter Aortic Valve Replacement (TAVR)*

**Published**: 08/01/2019

**Next Review:** 09/2019

**Last Review:** 07/2019 ***Medicare Link(s) Revised:*** *08/01/2019*

***IMPORTANT REMINDER***

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.*

*The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.*

## DESCRIPTION

"Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve." *(NCD 20.32)*

| MEDICARE ADVANTAGE POLICY CRITERIA | |
|---|---|
| **Procedure(s):** | **CMS Coverage Manuals and National Coverage Determinations (NCD)*** |
| ***General coverage criteria*** | Transcatheter Aortic Valve Replacement (TAVR) (20.32) (While general criteria can be found in the NCD, the Medicare *Decision Memo for Transcatheter Aortic Valve Replacement [TAVR] [CAG-00430R]*, dated 06/21/2019, provides criteria changes, which are reflected in the rows below.)<br><br>*(When NCD 20.32 is updated with the changes outlined in this Decision Memo, the Decision Memo will be removed from the policy.)* |
| **ADDITIONAL GUIDELINES:** | |
| ***For the treatment of symptomatic aortic valve stenosis and when furnished according to a Food and Drug Administration (FDA)-approved indication*** | • The indication for coverage is symptomatic aortic valve stenosis; ***AND***<br>• The device is FDA approved for symptomatic aortic stenosis; ***AND***<br>• A cardiac surgeon and an interventional cardiologist 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 *(In June 2019, there was a change by CMS published in the Final Decision Memo with respect to what providers are required to be involved in independent examinations to determine eligibility for TAVR. The changes are reflected here)*; ***AND***<br>• The interventional cardiologist and cardiac surgeon must jointly participate in the intraoperative technical aspects of TAVR; ***AND***<br>• The heart team and hospital are participating in a prospective, national, audited registry (see the CMS TAVR/TAVI Coverage with Evidence Development web page for the most current STS/ACC TVT Registry™ Registry link).[2] |
| ***For uses not expressly listed as FDA-approved indications*** | TAVR/TAVI for non-FDA approved indications requires patients be enrolled in CMS-approved qualifying clinical studies, which are also posted on the CMS TAVR/TAVI Coverage with Evidence Development web page.[2] |

| Procedure(s): | CMS Coverage Manuals and National Coverage Determinations (NCD)* |
|---|---|
| *(See the "Regulatory Status" section below for guidance regarding FDA-approval information)* | We recommend providers use the CMS Coverage Website to identify whether CMS (or a designated entity) has approved a study for purposes of Medicare coverage of a clinical trial or Investigational Device Exemption (IDE) study.<br><br>*For information regarding Category A and B IDEs and Coverage with Evidence Development (CED) guidelines, see Cross References.* |
| ***Repeat aortic valve replacement procedures*** | Paravalvular leaks and paravalvular regurgitation (PVR) are known complications of TAVR, and can lead to the need for a repeat aortic valve procedure.[3,4] The durability of TAVR valves has been established at 5-year follow up but the long-term durability remains unknown, so the Medicare NCD 20.32 requires registries to track various outcomes, including repeat aortic procedures as they collect data regarding the long-term safety and efficacy of TAVR procedures. The health plan will consider repeat TAVR procedures to be **medically necessary** for paravalvular regurgitation (PVR) or leaks when the National Clinical Trial (NCT) number of the registry is included, in order to meet the NCD registry requirement for tracking repeat valve procedures. |

## POLICY GUIDELINES

### REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- All clinical documentation pertinent to request, including condition to be treated, documentation of two (2) cardiac surgeons having examined the patient's suitability for open aortic valve replacement with the rationale for their judgment, and confirmation the patient is under the care of a heart team;
- The name of the device that will be used; and,
- The NCT number for the registry or study the member is enrolled in (enrollment is a requirement under the Medicare NCD). This is also required for ***repeat*** TAVR procedures.

### REGULATORY STATUS

For FDA approved indications for various devices, see the FDA website.[5,6]

## CROSS REFERENCES

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

## REFERENCES


1. Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, §290 – Transcatheter Aortic Valve Replacement (TAVR) *(and all related subsections)*
2. CMS Manual System Change Request 7897 Dated September 24, 2012
3. Medicare Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430N) [Last Cited 05/15/2019]
4. Medicare Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R) [Last Cited 07/03/2019]
5. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data for the Edwards SAPIEN™ Transcatheter Heart Valve
6. FDA Summary of Safety and Effectiveness Data for the Medtronic CoreValve™ System Transcatheter Aortic Valve (TAV)


## CODING

**NOTE:** There are various approaches for performing TAVR, and many of those approaches have a specific CPT code available. However, there is no specific code for TAVR performed via the carotid artery. Therefore, the appropriate code for reporting this procedure is 33999.

| Codes | Number | Description |
|---|---|---|
| **CPT** | 33361 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach |
| | 33362 | ; open femoral approach |
| | 33363 | ; open axillary artery approach |
| | 33364 | ; open iliac artery approach |
| | 33365 | ; transaortic approach (e.g., median sternotomy, mediastinotomy) |
| | 33366 | ; transapical exposure (e.g., left thoracotomy) |
| | 33999 | Unlisted procedure, cardiac surgery |
| **HCPCS** | None | |

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*