


<b>MEDICAL POLICY</b>	<b>Cardiac: Transcatheter Aortic Valve Replacement (TAVR) (Medicare Only)</b>
<b>Effective Date: 8/1/2022</b>	Medical Policy Number: 221
 8/1/2022	Medical Policy Committee Approved Date: 10/18; 11/19; 5/2020; 7/2021; 11/2021; 7/2022
Medical Officer	Date

**See Policy CPT CODE section below for any prior authorization requirements.**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).


**APPLIES TO:**

Medicare only

**DOCUMENTATION REQUIREMENTS**

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- All clinical documentation pertinent to request, including:
  - Condition to be treated;
  - Documentation of two (2) specialists having examined the patient’s suitability for valve replacement and the rationale for their judgment (the NCDs in this Medicare Advantage medical policy provide specific requirements regarding which specialists are to independently examine the patient – these NCD requirements will be used as appropriate for the request); 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 or provider is enrolled in (enrollment is a requirement under the Medicare NCD).

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**MEDICARE POLICY CRITERIA**

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
<i>Transcatheter Aortic Valve Replacement (TAVR)</i>	<p>National Coverage Determination for Transcatheter Aortic Valve Replacement (TAVR) (<a href="#">20.32</a>)</p> <p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>• Both Food and Drug Administration (FDA) approved and non-approved uses may be eligible for coverage under this NCD when performed within a Medicare-approved clinical study, registry or trial. This includes the use of a TAVR device to replace a degenerated or failed bioprosthetic valve (aka, a valve-in-valve procedure). <ul style="list-style-type: none"> <li>○ A list of Medicare-approved registries and clinical trials which have been reviewed and determined to meet Medicare’s requirements can be found on the <a href="#">Medicare CED Transcatheter Aortic Valve Replacement web page</a>.</li> </ul> </li> <li>• See <a href="#">Table 1</a> below for a list of FDA-approved devices.</li> </ul>

**POLICY GUIDELINES**

Medicare and Medical Necessity

Services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*) This includes the use of medical devices which have **not** received the necessary regulatory approval (see *Regulatory Status* below).

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Society of Thoracic Surgeons (STS) Risk Calculator <sup>3,4</sup>

The Society of Thoracic Surgeons (STS) cardiac surgery risk model for isolated valve surgery is a risk assessment tool that adjusts cardiac surgery outcomes for preoperative patient characteristics and disease severity. This tool is an online tool that can be used to assess the risk of open surgical valve replacement and is included as part of the FDA indications for FDA-approved aortic valve replacement systems. The online risk calculator is publicly available from [The Society of Thoracic Surgeons website](#).<sup>5</sup>

**BILLING GUIDELINES**

The *Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services*, [§290 – Transcatheter Aortic Valve Replacement \(TAVR\)](#) provides coding and billing guidance, both prior to January 1, 2013 and coding as of January 1, 2013. Because this Medicare NCD allows coverage of TAVR under the Coverage with Evidence Development (CED) provision, additional requirements regarding specific modifier and diagnosis code are in place and detailed in this Medicare coverage manual.

Medicare also requires the 8-digit identifier number to be included on claims for TAVR. Registry and study numbers can be found on the [Medicare CED Transcatheter Aortic Valve Replacement web page](#).

**CPT CODES**

Medicare Only	
No Prior Authorization Required	
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)

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33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)
<b>Unlisted Codes</b> All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then <b>prior-authorization is required.</b>	
33999	Unlisted procedure, cardiac surgery
93799	Unlisted cardiovascular service or procedure

**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.

**INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

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## REGULATORY STATUS

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

### U.S. Food and Drug Administration (FDA)

From the [Medicare Decision Memo CAG-00430R](#):

“On November 2, 2011 the FDA approved the first TAVR device for marketing in the United States. The Edwards’ SAPIEN Transcatheter Heart Valve (THV) was approved "for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open AVR and in whom existing co- morbidities would not preclude the expected benefit from correction of the aortic stenosis"... Since this first approval, devices have been approved for:

- Lower surgical risk groups, including high and intermediate;
- Alternate access sites, such as transapical and transaortic; and
- Valve-in-valve use for failed surgical bioprosthetic valves.”

**Table 1. FDA-Approved TAVR Devices**

*Note:* This table is pulled from the [Medicare Decision Memo CAG-00430R](#) and may not necessarily be up-to-date or all-inclusive of all devices.

Approval Date	Device	Implant Site	Indication Risk Stratum
11/02/2011	Edwards SAPIEN	Native	Inoperable (transfemoral access only)
10/19/2012	Edwards SAPIEN	Native	High risk (transfemoral access only)
09/23/2013	Edwards SAPIEN	Native	Alternate access labeling expansion
01/17/2014	Medtronic CoreValve	Native	Extreme risk
06/12/2014	Medtronic CoreValve	Native	High risk
06/16/2014	Edwards SAPIEN XT	Native	High risk and above
03/30/2015	Medtronic CoreValve	Valve-in-valve	High risk and above
06/17/2015	Edwards SAPIEN 3	Native	High risk and above
06/22/2015	Medtronic CoreValve Evolut R	Native and valve-in-valve	High risk and above

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10/09/2015	Edwards SAPIEN XT	Valve-in-valve	High risk and above
08/18/2016	Edwards SAPIEN XT	Native	Intermediate risk
08/18/2016	Edwards SAPIEN 3	Native	Intermediate risk
10/19/2012	Edwards SAPIEN	Native	High risk (transfemoral access only)
03/20/2017	Medtronic CoreValve Evolut PRO	Native and valve-in-valve	High risk and above
06/05/2017	Edwards SAPIEN 3	Valve-in-valve	High risk and above
07/10/2017	Medtronic CoreValve, CoreValve Evolut R, and CoreValve PRO	Native	Intermediate risk
12/28/2018	Edwards Sapien 3 Ultra	Native and valve-in-valve	Intermediate risk or above
04/23/2018	Boston Scientific LOTUS Edge Valve System	Native	High risk and above

The following devices have not been FDA-approved and are currently considered not medically necessary:

- ACURATE TA™ system (Boston Scientific)
- Engager TAVI system (Medtronic)
- JenaValve transapical (TAVI) system (JenaValve Technology)
- Portico™ Transcatheter Aortic Valve (St. Jude Medical)

**MEDICAL POLICY CROSS REFERENCES**

- Clinical Trials and IDE Studies (Medicare Only)
- Cardiac: Transcatheter Aortic Valve Replacement (TAVR) (All Lines of Business Except Medicare)

**REFERENCES**

1. O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2--isolated valve surgery. Ann Thorac Surg. 2009;88(1 Suppl):S23-42. <https://www.ncbi.nlm.nih.gov/pubmed/19559823>.
2. Shahian DM, Edwards FH. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: introduction. Ann Thorac Surg. 2009;88(1 Suppl):S1. <https://www.ncbi.nlm.nih.gov/pubmed/19559821>.
3. The Society for Thoracic Surgeons. Risk Model and Variables. Online STS Adult Cardiac Surgery Risk Calculator. Database Version 2.81. <http://riskcalc.sts.org/stswebriskcalc/#/calculate>. Accessed 5/25/2021.