

# Medicare Medical Policy

## Cardiac: Transcatheter Aortic Valve Replacement (TAVR)

MEDICARE MEDICAL POLICY NUMBER: 221

|                                   |                                     |   |
|-----------------------------------|-------------------------------------|---|
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**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

**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”).

## PRODUCT AND BENEFIT APPLICATION

Medicare Only

### MEDICARE COVERAGE CRITERIA

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

| 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> |

**IMPORTANT NOTICE:** While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

### POLICY CROSS REFERENCES

- [Clinical Trials and IDE Studies](#), MP233
- [Cardiac: Transcatheter Aortic Valve Replacement \(TAVR\)](#), MP77

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### 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).

### BACKGROUND

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.

### 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).

### 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>

## REGULATORY STATUS

### U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

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                   |
| 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                   |

|                   |  |                           |                            |
|-------------------|--|---------------------------|----------------------------|
| <b>07/10/2017</b> | Medtronic CoreValve, CoreValve Evolut R, and CoreValve PRO | Native                    | Intermediate risk          |
| <b>12/28/2018</b> | Edwards Sapien 3 Ultra                                     | Native and valve-in-valve | Intermediate risk or above |
| <b>04/23/2018</b> | 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)

## BILLING GUIDELINES AND CODING

### GENERAL

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](#).

| CODES* |       |   |
|--------|-------|---|
| CPT    | 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) |

|              |       |   |
|--------------|-------|---|
|              | 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) |
|              | 33999 | Unlisted procedure, cardiac surgery   |
|              | 93799 | Unlisted cardiovascular service or procedure  |
| <b>HCPCS</b> | None  |   |

**\*Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## 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.

## POLICY REVISION HISTORY

| DATE | REVISION SUMMARY |
|------|------------------|
|------|------------------|

