Medicare Medical Policy

Transcatheter Aortic Valve Replacement (TAVR)

MEDICARE MEDICAL POLICY NUMBER: 221

Effective Date: 7/1/2024

Last Review Date: 6/2024

Next Annual Review: 6/2025

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, and Providence Plan Partners 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
Transcatheter Aortic Valve Replacement (TAVR)	National Coverage Determination for Transcatheter Aortic Valve Replacement (TAVR) (20.32) • **Criterion B.A.** addresses TAVR for symptomatic aortic valve stenosis when the TAVR system is used according to an U.S. Food and Drug Administration (FDA) approved indication. • **Criterion B.B.** addresses TAVR for uses **not** listed as an FDA-approved indication for use. **NOTES:** • TAVR is also known as transcatheter aortic valve implantation (TAVI). • Both Food and Drug Administration (FDA) approved and non- approved uses may be eligible for coverage under this NCD. Both situations require services be 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). ○ Medicare-approved registries and clinical trials can be found on the Medicare CED Transcatheter Aortic Valve Replacement web page. • See Table 1 below for a list of FDA-approved devices.

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, Studies, and Registries, MP233

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." *(NCD 20.32)*

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[1,2]

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.[3]

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 Aortic Valve and Implantation Systems

Note: List may not be all inclusive or up-to-date. Please refer to the U.S. Food & Drug Administration (FDA) website for additional information. FDA Product Code: NPT

Device	Indications	Contraindications
Edwards Sapien XT (by Edwards Lifesciences LLC.)	• The Edwards SAPIEN XT transcatheter heart valve, model 9300TFX, and accessories are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-	The valve and delivery system are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

	morbidities unmeasured by the STS risk calculator). • The Edwards SAPIEN XT transcatheter heart valve and accessories are also indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., STS operative risk score ≥8% or at a ≥15% risk of mortality at 30 days).	
Edwards Sapien 3 (by Edwards Lifesciences LLC.)	• The Edwards SAPIEN 3 transcatheter heart valve, Model 9600TFX, and accessories are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be 5 at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator). • The Edwards SAPIEN 3 transcatheter heart valve, Model 9600TFX, and accessories are indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30	The valve and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

	days, based on the STS risk score and other clinical comorbidities unmeasured by the STS risk calculator).	
CoreValve (by Medtronic)	The Medtronic CoreValve, CoreValve Evolut R, CoreValve Evolut PRO systems are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).	The Medtronic CoreValve, CoreValve Evolut R, CoreValve Evolut PRO systems are contraindicated for patients presenting with any of the following conditions: • Known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or sensitivity to contrast media, which cannot be adequately premedicated • Ongoing sepsis, including active endocarditis Pre-existing mechanical heart valve in aortic position
LOTUS Edge™ Valve System (by Boston Scientific)	The LOTUS Edge™ Valve System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area [AVA] of ≤ 1.0 cm2 or index of ≤ 0.6 cm2 /m2) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).	The LOTUS Edge™ Valve System is contraindicated in patients who have: a non-calcified aortic annulus; an active systemic infection, sepsis, or endocarditis; known hypersensitivity to contrast agents that cannot be adequately pre-medicated, or known hypersensitivity or contraindication to aspirin, thienopyridines, heparin, nickel, titanium, tantalum, bovine-derived materials or polyurethanes; or severe arterial tortuosity or calcification that would prevent safe placement of the introducer sheath.
Portico Transcatheter Aortic Valve Implantation System (Abbot)	The Portico Transcatheter Aortic Valve Implantation System is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe	The valve is contraindicated for patients with inability to tolerate antiplatelet/anticoagulant

	native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at **high or greater risk** for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).	therapy, nitinol alloy (nickel and titanium), or who have active infections, including endocarditis.

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)

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
HCPCS	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
8/2022	Annual review (converted to new format 2/2023)
7/2023	Annual review; no changes
7/2024	Annual review; no changes