

Transcatheter Aortic Valve Replacement (TAVR)

Policy Number: **M20121214042**
Effective Date: **1/1/2013**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☐ Child Health Plus ☒ Essential Plan
☐ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☐ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth the coverage and clinical criteria utilized for the authorization of a **transcatheter (percutaneous) aortic valve replacement (TAVR)**.

Policy:

Self-Funded:

Severe aortic stenosis is defined by one or more of the following criteria:

- An aortic valve area of less than ≤ 1.0 cm²
- An aortic valve area index of less than or equal to 0.6 cm²/m²
- A mean aortic valve gradient greater than 40mmHg
- An echocardiographic Doppler jet velocity greater than 4.0m/sec

Medical Necessity:

TAVR is considered medically necessary when all the following conditions are present:

- Severe aortic stenosis; and
- **New York Heart Association (NYHA)** Heart Failure Class II, III or IV symptoms
- Members with severe symptomatic calcified **native** aortic valve stenosis without severe aortic insufficiency; and
- Members with an ejection fraction >20% who have been examined by a **heart team** including both an experienced cardiac surgeon and a cardiologist who find the member:
 1. *inoperable* and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis; or
- The procedure is performed with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.

Contraindications:

The prosthetic valve and delivery system are contraindicated in members who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Service Requirements: The procedure is performed in a facility and by physicians that meets the institutional requirements set forth in the Centers for Medicare and Medicaid Service National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR). NCD reference available below.

Medicare Advantage:

Managed by Evolent

MediSource, MediSource Connect, and Essential Plan:

MediSource, MediSource Connect, and Essential Plan cover TAVR utilizing the Commercial criteria above.

Investigational and Not Medically Necessary: Transcatheter aortic valve replacement is considered investigational and not medically necessary when all the criteria specified above are not met, or for the treatment of all other conditions.

Background:

Transcatheter heart valve replacement is an alternative treatment to an open surgical procedure for members with severe aortic stenosis (AS). Aortic stenosis is the most common valve disorder in the United States. Progressive calcification of the aortic valve is the most common etiology in North America. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension and hyperlipidemia.

Aortic stenosis involves a long asymptomatic period, with slowly progressive narrowing of the valve until the stenosis reaches the severe stage. Symptoms of chest pain, dyspnea, dizziness / syncope often occur as the disorder progresses. By the time AS reaches the severe stage there is an untreated mortality rate of 50% within two years. Open treatment with artificial valves has been an effective treatment; however, due to the severity of the disease and co-morbidities the eligible members are poor candidates for an open procedure.

In a TAVR procedure a catheter is inserted percutaneously using a transfemoral or transapical approach which allows the introduction of an expandable prosthetic heart valve to be implanted into the orifice of the diseased valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on a beating heart without the need of cardiopulmonary bypass.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization not required. Criteria utilized upon retro-review.

Definitions

Aortic valve stenosis (AS): also, known as aortic stenosis is a form of valvular heart disease characterized by narrowing of the aortic valve opening resulting in obstruction of blood flow from the left ventricle into the ascending aorta.

Heart Team: a cohesive, multi-disciplinary team of medical professionals that embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

Native valve: relating or belonging to a person or thing by conditions existing at the time of birth.

The New York Heart Association (NYHA) Functional Classification: provides a simple way of classifying the extent of heart failure. It places patients in one of four categories based on how much they are limited during physical activity; the limitations/symptoms are in regard to normal breathing and varying degrees in shortness of breath and or angina pain:

NYHA Class Symptoms

- I - Cardiac disease, but no symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
- II - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
- III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.

- IV - Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Society of Thoracic Surgeons predicted operative risk score allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

Transcatheter (percutaneous) aortic valve replacement (TAVR) uses percutaneous access through a peripheral artery to place a bioprosthetic valve within the stenotic aortic valve.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Bavaria JE, Tommaso CL, Brindis RG, et al. 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement: A Joint Report of the American Association for Thoracic Surgery, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. 2019 Jan 29;73(3):340-374.

Brecker S, Aldea GS, Choice of intervention for severe calcific aortic stenosis. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on July 17, 2024)

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Vahanian A, Beyersdorf F, Praz F, et al; ESC/EACTS Scientific Document Group. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022 Feb 12;43(7):561-632.

Writing Committee Members, Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2021 Feb 2;77(4):e25-e197.

Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32). Available at: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=355&ncdver=2&keyword=transcatheter%20aortic&keywordType=starts&areald=s65&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAA AAAQAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact> Accessed July 1, 2025.

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Code Manual. Physician Surgery Procedure Codes, July 2024. Available at: <https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf> Accessed: July 1, 2025.

United States Food and Drug Administration (FDA) [web site]. Approval letter August 7, 2012. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf11/p110021a.pdf Accessed July 1, 2025.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
11/1/2025	Health Care Services	Revised
11/1/2024	Health Care Services	Revised
9/1/2024	Health Care Services	Reviewed
9/1/2023	Health Care Services	Revised
9/1/2022	Health Care Services	Revised
9/1/2021	Health Care Services	Reviewed
9/1/2020	Health Care Services	Revised
10/1/2019	Medical Management	Revised
5/1/2019	Medical Management	Revised
5/1/2018	Medical Management	Revised
5/1/2017	Medical Management	Revised

6/1/2016	Medical Management	Revised
7/1/2015	Medical Management	Revised
4/1/2015	Medical Management	Revised
2/1/2014	Medical Management	Revised