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2025 Transcatheter Aortic Valve Replacement/Implant (TAVR/I) BCBSSC

Cardiology

CARD-CTAV-BCBSSC

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Contraindications or Exclusions to TAVR/I

TAVR/I is considered contraindicated or excluded when the documentation demonstrates **ANY** of the following:

- Aortic arch atherosclerotic (protuberant lesions)
- Aorto-iliac occlusive disease (precluding transfemoral approach)
- Basal septal hypertrophy
- Clinical status makes procedure inappropriate (eg, endocarditis)
- Coronary arteries are low-lying.
- Frailty (See the "Clinical Frailty Scale" in the Definition Section)
- Hepatic dysfunction
- Left ventricular outflow tract with extensive calcification
- Mitral or tricuspid regurgitation is severe.
- Pulmonary disease is severe (eg, chronic obstructive pulmonary disease [COPD], home oxygen used).
- Pulmonary hypertension
- Rehabilitation candidacy is poor (eg, low exercise tolerance).
- Right ventricle dysfunction is severe.
- Society of Thoracic Surgeons (STS) score is over 15.
- Valve morphology (eg, bicuspid or unicuspid valve)
  References: [5]

Transcatheter Aortic Valve Replacement/Implant (TAVR/I)

NCD 20.32
Coverage criteria for this NCD has administrative indications for consideration.
See also, **NCD 20.32**: Transcatheter Aortic Valve Replacement (TAVR) at https://www.cms.gov/medicare-coverage-database/search.aspx *if applicable to individual's healthplan membership*.

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Preamble: Pediatric Cardiology Preamble

HealthHelp's clinical guidelines for the Cardiology program, are intended to apply to both adults and pediatrics (21 years of age or younger), unless otherwise specified within the criteria.

TAVR/I Guideline

Transcatheter aortic valve replacement/implant (TAVR/I) for valvular heart disease is considered medically appropriate when the documentation demonstrates **ALL** of the following:

1. Aortic regurgitation and stenosis are combined and peak transvalvular jet velocity of 4.0 m/s or more **OR** mean transvalvular gradient of 40 mm Hg or more.
   Reference: [5]
2. Aortic stenosis (AS) is severe, based on New York Heart Association (NYHA) classification II or higher, and **ANY** of the following:
   a. Bicuspid aortic valve is known and **ALL** of the following:
      i. Performed at a comprehensive valve center
      ii. Risk evaluation of **ALL** of the following:
         A. Aortic dilation more than 5.5 cm
         B. Rapid progression of dilation [more than 3 mm/year]
         C. Family history of aortic dissection
      iii. Symptomatic (eg, chest pain, dizziness, shortness of breath)
   b. **NO** anatomic contraindications to TAVI (aneurysm, aortic stent graft is present, chronic dissection, extreme tortuosity, large thrombus, peripheral artery disease [PAD], previous vascular surgery) and **ANY** of the following:
      i. Age is 65 to 80 years old
      ii. Age is 80 years or less **AND** left ventricular ejection fraction (LVEF) is less than 50%.
      iii. Age is more than 80 years old **OR** life expectancy is less than 10 years
   c. Surgical risk is high or prohibitive and **ANY** of the following:
      i. **ALL** of the following:
         A. Comorbidities predict risk of operative mortality is 15% or more
         B. Predicted operative mortality or serious, irreversible morbidity risk of 50% or less, at 30 days.

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C. Per agreement between 1 cardiologist and 2 cardiac surgeons

ii. Aortic valve disease is known, in a pediatric individual.

References: [5] [4] [3] [1] [2]

TAVR/I Procedure Codes

Table 1. Transcatheter Aortic Valve Replacement (TAVR/TAVI Associated Procedure Codes

CODE	DESCRIPTION
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)

TAVR/I Summary of Changes

Transcatheter Aortic Valve Replacement (TAVR) clinical guidelines from 2024 to 2025 had the following version changes:

- Added the following to keep in line with current research per the American College of Cardiology/American Heart Association Joint Committee.
  - "Bicuspid aortic valve" indication
  - Pediatric indications and pediatric preamble
  - Contraindications or Exclusions to TAVR/I
    - Aortic arch atherosclerotic (protuberant lesions)
    - Aorto-iliac occlusive disease (precluding transfemoral approach)
    - Basal septal hypertrophy
    - Clinical status makes procedure inappropriate (eg, endocarditis)
    - Coronary arteries are low-lying.
    - Frailty (See the "Clinical Frailty Scale" in the Definition Section)
    - Hepatic dysfunction

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- Left ventricular outflow tract with extensive calcification
- Mitral or tricuspid regurgitation is severe.
- Pulmonary disease is severe (eg, chronic obstructive pulmonary disease [COPD], home oxygen used)
- Pulmonary hypertension
- Rehabilitation candidacy is poor (eg, low exercise tolerance).
- Right ventricle dysfunction is severe.
- Society of Thoracic Surgeons (STS) score is over 15
- Valve morphology (eg, bicuspid or unicuspid valve)

- Changed indications under "Aortic stenosis" to keep in line with current research per the American College of Cardiology/American Heart Association Joint Committee.
- Removed the following as current research no longer supports the indication per the American College of Cardiology/American Heart Association Joint Committee
  - "Biprosthetic valve replacement" indication
  - Life expectancy is under 1 year (removed because it is an assumed parameter if the test is ordered)

TAVR/I Definitions

Aortic regurgitation is characterized by the abnormal retrograde flow of blood from the aorta into the left ventricle during diastole due to improper closure of the aortic valve.
Aortic valve area (AVA) is a measure of the orifice size of the aortic valve, with normal values ranging from 3 to 4 cm². Severe aortic stenosis is defined by an AVA of less than 1 cm².
Aortic valve stenosis (AVS) is a congenital or acquired disorder of the aortic valve leading to abnormal narrowing of the orifice and increased impedance to the flow of blood out of the heart into the aorta.

Table 1. Atrial Stenosis (AS) Stage Classifications[a.]

Stage	Definition	Valve Anatomy	Valve Hemodynamics and Hemodynamic Consequences	Symptoms
A	At Risk	Congenital valve anomaly (eg, bicuspid aortic valve [BAV])	• Aortic V_{max} < 2 m/s with normal leaflet motion	• None

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Stage	Definition	Valve Anatomy	Valve Hemodynamics and Hemodynamic Consequences	Symptoms
B	Progressive	Mild to moderate leaflet calcification/fibrosis of a bicuspid or trileaflet valve with some reduction in systolic motion or Rheumatic valve changes with commissural fusion	• Mild AS: aortic V_{max} 2.0–2.9 m/s or mean ΔP < 20 mm Hg • Moderate AS: aortic V_{max} 3.0–3.9 m/s or mean ΔP 20–39 mm Hg • Early left ventricular (LV) diastolic dysfunction may be present, normal left ventricular ejection fraction (LVEF)	• None
C1	Asymptomatic, severe	Severe leaflet calcification/ fibrosis or congenital stenosis with severely reduced leaflet opening	• Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg • AVA typically ≤1.0 cm^2 (or AVAi 0.6 cm^2/m^2) but not required to define severe AS • Very severe AS is an aortic V max ≥5 m/s or mean P ≥60 mm Hg • LV diastolic dysfunction, mild LV hypertrophy, normal LVEF	• None, exercise testing reasonable to confirm symptom status
C2	Asymptomatic, severe with LV systolic dysfunction	Severe leaflet calcification/ fibrosis or congenital stenosis with severely reduced leaflet opening	• Aortic Vmax ≥4 m/s or mean ΔP ≥40 mm Hg • AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but not required to define severe AS • LVEF <50%	• None
D1	Symptomatic, severe, high-gradient	Severe leaflet calcification/ fibrosis or congenital stenosis with severely reduced leaflet opening	• Aortic Vmax ≥4 m/s or mean ΔP ≥40 mm Hg • AVA typically ≤1.0 cm^2 (or AVAi ≤0.6 cm^2/m^2) but may be larger with mixed AS/AR • LV diastolic dysfunction, LV hypertrophy, pulmonary hypertension may be present	• Angina, exertional • Dyspnea on exertion • Exercise tolerance decreased • Heart failure • Syncope or presyncope on exertion

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Stage	Definition	Valve Anatomy	Valve Hemodynamics and Hemodynamic Consequences	Symptoms
D2	Symptomatic, severe, low-flow, low-gradient with reduced LVEF	Severe leaflet calcification/ fibrosis with severely reduced leaflet motion	• AVA ≤1.0 cm^2 with resting aortic V_{max} < 4 m/s or mean ΔP <40 mm Hg • Dobutamine stress echocardiography shows AVA <1.0 cm^2 with V_{max} ≥4 m/s at any flow rate • LV diastolic dysfunction, LV hypertrophy, LVEF <50%	• Angina • Heart failure • Syncope/ presyncope
D3	Symptomatic, severe, low-gradient with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification/ fibrosis with severely reduced leaflet motion	• AVA ≤1.0 cm^2 (indexed AVA ≤0.6 cm^2 /m^2) with an aortic Vmax <4 m/s or mean ΔP < 40 mm Hg **AND** Stroke volume index <35 mL/m^2 measured when normotensive (systolic blood pressure <140 mm Hg) • Increased LV relative wall thickness, small LV chamber with low stroke volume, restrictive diastolic filling, LVEF ≥50%	• Angina • Heart failure • Syncope/ presyncope

[a]·Otto C, Nishimura R, Bonow R, 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. Circulation 143(5), pp. e72-e227; December 17, 2020.

Aortic valve stenosis repair refers to procedures aimed at correcting the narrowing of the aortic valve, which obstructs blood flow from the left ventricle to the aorta.

Bicuspid aortic valve is an inherited form of heart disease in which two of the three leaflets of the aortic valve fuse together during development in utero, creating a less efficient two leaflet valve. The aortic valve plays a crucial role in ensuring the unidirectional flow of blood from

Clinical Frailty Scale:

- Very Fit – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.
- Well– People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, eg, seasonally.
- Managing Well – People whose medical problems are well controlled, but are not regularly active beyond routine walking
- Vulnerable – While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up" and/or being tired during the day.

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- Mildly Frail – These people often have more evident slowing, and need help in high order IADLs (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.
- Moderately Frail – People need help with all outside activities and with keeping house. Inside, they often have problems with stairs, need help with bathing and might need minimal assistance (cuing, standby) with dressing.
- Severely Frail – Completely dependent for personal care from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).
- Very Severely Frail – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

Hemodynamics refers to the study of the relationship between blood pressure, cardiac output, and vascular resistance, and how these factors influence the circulation of blood within the cardiovascular system.

Left ventricular ejection fraction (LVEF), also known as ejection fraction (EF), is defined as the percentage of blood ejected from the left ventricle during each contraction.

New York Heart Association (NYHA) Functional Classification is a tool used to classify an individual's heart failure according to the severity of their symptoms, as follows:

Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).

Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).

Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.

Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Source: https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure

Society of Thoracic Surgeons (STS) score is a screening tool used for patients being considered for cardiac surgery. The tool incorporates STS risk models and is designed to account for the impact of patient risk factors on operative mortality and morbidity.

The Society for Thoracic Surgeons (STS), "Risk-Calculator." [Online]: Available: https://acsdriskcalc.research.sts.org/

Transcatheter aortic valve replacement (TAVR), also known as **transcatheter aortic valve implantation (TAVI)**, is a minimally invasive procedure used to replace a stenotic aortic valve in patients with severe symptomatic aortic stenosis, particularly those at high surgical risk.

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Transvalvular jet velocity, also known as **peak transvalvular velocity (Vmax)**, is the highest systolic velocity of blood across the aortic valve. It's a measurement that can be used to assess the severity of aortic stenosis (AS).

TAVR/I References

[1] Adams, D.H. (2022). Safety and Efficacy Study of the Medtronic CoreValve® System in the Treatment of Symptomatic Severe Aortic Stenosis in High Risk and Very High Risk Subjects Who Need Aortic Valve Replacement. *ClinicalTrials.gov*. Retrieved: 10/2024. https://clinicaltrials.gov/study/NCT01240902

[2] (2024). Are there pediatric specific indications for transcatheter aortic valve replacement?. *Clinical Key*. Retrieved: December 2024. https://ai.clinicalkey.com/ask/27e29e61-6784-45b1-8d7c-3a277ed78eb8

[3] Hudziak, D., Targonski, R., . . . Jagielak, D. (2023). Comparison of transcarotid versus transapical transcatheter aortic valve implantation outcomes in patients with severe aortic stenosis and contraindications for transfemoral access. *Cardiology Journal, 30*(2), 188-195.

[4] Longobardo, L., Carerj, S., . . .Zito, C. (2021). Bicuspid aortic valve and aortopathy: novel prognostic predictors for the identification of high-risk patients. *European Heart Journal: Cardiovascular Imaging, 22*(7), 808-816.

[5] Otto, C. M., Nishimura, R. A., . . .Toly, C. (2021). 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. *Journal of the American College of Cardiology, 77*(4), 450–500.

Disclaimer section

Purpose

The purpose of the HealthHelp's clinical guidelines is to assist healthcare professionals in selecting the medical service that may be appropriate and supported by evidence to safely improve outcomes. Medical information is constantly evolving, and HealthHelp reserves the right to review and update these clinical guidelines periodically. HealthHelp reserves the right to include in these guidelines the clinical indications as appropriate for the organization's program objectives. Therefore the guidelines are not a list of all the clinical indications for a stated procedure, and associated Procedure Code Tables may not represent all codes available for that state procedure or that are managed by a specific client-organization.

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Clinician Review

These clinical guidelines neither preempt clinical judgment of trained professionals nor advise anyone on how to practice medicine. Healthcare professionals using these clinical guidelines are responsible for all clinical decisions based on their assessment. All Clinical Reviewers are instructed to apply clinical indications based on individual patient assessment and documentation, within the scope of their clinical license.

Payment

The use of these clinical guidelines does not provide authorization, certification, explanation of benefits, or guarantee of payment; nor do the guidelines substitute for, or constitute, medical advice. Federal and State law, as well as member benefit contract language (including definitions and specific contract provisions/exclusions) take precedence over clinical guidelines and must be considered first when determining eligibility for coverage. All final determinations on coverage and payment are the responsibility of the health plan. Nothing contained within this document can be interpreted to mean otherwise.

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National and Local Coverage Determination (NCD and LCD)

NOTICE
To ensure appropriate review occurs to the most current NCD and/or LCD, always defer to https://www.cms.gov/medicare-coverage-database/search.aspx.

Background

National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) are payment policy documents outlined by the Centers for Medicare and Medicaid Services (CMS) and the government's delegated Medicare Audit Contractors (MACs) that operate regionally in jurisdictions.

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CMS introduced variation between different jurisdictions/Medicare Audit Contractors (MACs) and their associated covered code lists with the transition to ICD 10. The variation resulted in jurisdictions independently defining how codes are applied for exclusions, limitations, groupings, ranges, etc. for the medical necessity indications outlined in the NCD and LCD. Due to this variation, there is an inconsistent use/application of codes and coverage determinations across the United States between the different MACs.

In addition, **WITHOUT** notice, CMS can change the codes that indicate medical necessity and the format of the coverage determinations/associated documents (eg, Articles). This is an additional challenge for organizations to keep up with ongoing, unplanned changes in covered codes and medical necessity indications.

Medical Necessity Codes

Due to the variation in code application between jurisdictions/MACs and that updates can happen without notification, HealthHelp is not able to guarantee full accuracy of the codes listed for any Coverage Determination, and advises that prior to use, the associated Coverage Determination Articles are reviewed to ensure applicability to HealthHelp's programs and any associated NCDs and LCDs.

For Internal Use Only:

11248 11249 11253 11282 11325 11328 11333 11349 11350 11351 11352 11354 11355 11356 11358 11359 11360 11361 11362 11365 11366 11367 11368 11369 11370 11374 11375 11394 11395 11396 11565

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