Cohere Medical Policy - Transcatheter Aortic Valve Replacement/Implantation (TAVR/TAVI)

Clinical Policy for Medical Necessity Review

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Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Policy Information:

Specialty Area: Cardiovascular Disease
Policy Name: Cohere Medical Policy - Transcatheter Aortic Valve Replacement/Implantation (TAVR/TAVI)
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Transcatheter Aortic Valve Replacement/Implantation (TAVR/TAVI)

Cohere Health takes an evidence-based approach to reviewing imaging and procedure requests, meaning that sufficient clinical information must be provided at the time of submission to determine medical necessity. Documentation must include a recent and detailed history, physical examination related to the onset or change in symptoms, relevant lab results, prior imaging, and details of previous treatments. Advanced imaging or procedures should be requested after a recent clinical evaluation by the treating provider, which may include referral to a specialist.

- When a specific clinical indication is not explicitly addressed in the Cohere Health medical policy, medical necessity will be determined based on established clinical best practices, as supported by evidence-based literature, peer-reviewed sources, professional society guidelines, and state or national recommendations, unless otherwise directed by the health plan.
- Requests submitted without clinical documentation, or those that do not align with the provided clinical information—such as mismatched procedure, laterality, body part, or CPT code—may be denied for lack of medical necessity due to insufficient or inconsistent clinical information.
- When there are multiple diagnostic or therapeutic procedures requested simultaneously or within the past three months, each will be reviewed independently. Clinical documentation must clearly justify all of the following:
  - The medical necessity of each individual request
  - Why prior imaging or procedures were inconclusive or why additional/follow-up studies are needed
  - How the results will impact patient management or treatment decisions
- Requests involving adjacent or contiguous body parts may be considered not medically necessary if the documentation demonstrates that the

patient's primary symptoms can be adequately assessed with a single study or procedure.

Description

Transcatheter aortic valve replacement/implantation (TAVR/TAVI) is an effective, minimally invasive catheter-based procedure to replace an aortic valve in patients with aortic valve stenosis. Patients considered for TAVR/TAVI include all risk cohorts (low- to high-risk). Compared to surgical aortic valve replacement (SAVR), TAVR has a lower risk of stroke, major bleeding, and atrial fibrillation, and a shorter hospital length of stay and shorter recovery.[1-8]

Medical Necessity Criteria

Indications

Transcatheter aortic valve replacement/implantation using a U.S. Food and Drug Administration (FDA) approved aortic valve (e.g., the SAPIEN 3 platform, the Medtronic Evolut TAVR platform, the Abbott Navitor TAVI System) is considered appropriate if **ANY** of the following is **TRUE**:

- For patients with severe symptomatic calcific aortic stenosis and **ANY** of the following[1,9-11]:
  - Aortic valve area is less than 1.0 cm^2 [1,10-11]; **OR**
  - Aortic valve area index is less than or equal to 0.6 cm^2/m^2 [1,10-11]; **OR**
  - Maximum Doppler velocity is greater than or equal to 4.0 m/s[1,9-11]; **OR**
  - Mean aortic valve gradient greater than or equal to 40 mm/Hg at rest[1,9-11]; **OR**
- For asymptomatic patients with severe calcific native aortic valve stenosis as indicated by **ALL** of the following[1,10]:
  - Peak systolic velocity of greater than or equal to 4.0 m/s or mean gradient of at least 40 mm/Hg[1]; **AND**
  - Severely restricted AV leaflet opening[1]; **AND**
  - Left ventricular ejection fraction (LVEF) less than or equal to 50%[1,10]; **AND**
  - Age between 65 and 80[1]; **OR**
- For symptomatic patients with suspected low flow/low gradient aortic stenosis and aortic valve calcium (AVC) of greater than or equal to 1300 Agaston units in women or 2000 Agaston units in men[1]; **OR**
- For valve-in-valve procedures for failed prior bioprosthetic valves, including **ANY** of the following[1,11]:

- The patient has a bioprosthetic aortic valve with aortic stenosis and/or aortic regurgitation, and **ALL** of the following are **TRUE**[1]:
  - The patient has symptomatic (e.g., fatigue, dyspnea, angina, syncope, or presyncope) severe stenosis[1]; **AND**
  - Improvement in hemodynamics is anticipated[1]; **OR**
- The patient has a bioprosthetic aortic valve with aortic regurgitation, and **ALL** of the following are **TRUE**[1,12]:
  - The patient has symptomatic (e.g., dyspnea, orthopnea) severe regurgitation; **AND**
  - Improvement in hemodynamics is anticipated.

Non-Indications

Transcatheter aortic valve replacement/implantation is not considered appropriate if **ANY** of the following is **TRUE**[1,8,12-16]:

- Life expectancy less than 12 months related to a non-cardiac cause[1]; **OR**
- Myocardial infarction within the last thirty days[15]; **OR**
- Valve with unsuitable anatomy for TAVR/TAVI, or noncalcified valve[1,13]; **OR**
- Hypertrophic obstructive cardiomyopathy[13]; **OR**
- A short distance between the annulus and coronary ostium for an artery unprotected by a bypass graft, and concern that TAVR/TAVI may result in coronary obstruction that cannot be protected[12,16]; **OR**
- Left ventricular ejection fraction less than 20%[13]; **OR**
- Severe pulmonary hypertension with right ventricular dysfunction determined to be not due to severe aortic stenosis and/or determined to be unlikely to improve after TAVR/TAVI[14]; **OR**
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation (unless completely healed)[13]; **OR**
- Severe primary mitral regurgitation without a plan to perform a transcatheter MitraClip procedure after TAVR/TAVI.[8]

Level of Care Criteria

Inpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve using percutaneous femoral

	artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve by median mediastinotomy
33366	Transcatheter aortic valve replacement (TAVR/TAVI) using prosthetic valve with transapical exposure

Medical Evidence

The severity of aortic stenosis is usually diagnosed based on echocardiographic parameters. Still, between 5 and 10% of patients with severe aortic valve stenosis do not meet these diagnostic criteria, typically patients with low-flow, low-gradient severe aortic stenosis. Sharma et al. (2023) reviewed how using ancillary testing may aid in identifying these patients, who could benefit from TAVR.[10]

Mesnier et al. (2022) reviewed the frequently increasing indications of TAVR. They found that indications for TAVR, which initially were confined to patients with severe symptomatic aortic stenosis, have now expanded to patients with high, intermediate, and even low surgical risk. As a result of this expansion, the number of TAVR procedures doubled compared to SAVR. They reason that the expansion of TAVR indications will continue, as several current randomized trials aim to expand TAVR indications.[9]

Otto et al. (2020) developed a guideline for the American College of Cardiology and the American Heart Association for managing patients with valvular heart disease. They state that surgical (SAVR) rather than transcatheter aortic valve replacement (TAVR) is recommended in patients less than 65 years of age due to lower surgical risk, but with a need for more extended valve durability. In patients older than 65, TAVR presents less surgical risk, pain, and hospital stay length than SAVR. At the same time, SAVR is associated with a lower risk of paravalvular leak, re-operation, and potential need for pacemaker implantation.[1]

Chen and colleagues (2018) studied 2032 patients in the PARTNER 2A (Placement of Aortic Transcatheter Valve) randomized trial to determine whether prior cardiac surgery was associated with increased surgical risk. These patients with severe aortic stenosis were determined to have intermediate surgical risk and were randomized between TAVR with the Sapien XT transcatheter valve versus SAVR. 25.1% of patients had prior cardiac surgery, with 98.2% of those being coronary artery bypass grafting. No significant differences were found between patients with TAVR versus SAVR in patients with or without prior cardiac surgery in 30 days up to 2 years.[3]

In 2018, Spaziano et al. prospectively studied TAVR in the catheterization laboratory vs a hybrid operating room. They stated that comparisons between these two locations were scarce. The primary endpoint of the FRANCE TAVI was all-cause mortality at one year, with secondary endpoints of 30-day complications and 3-year mortality. A total of 12,121 patients with a mean age of 82.9 years, and roughly even numbers of men and women were included in the study, with 62% undergoing TAVR in a catheterization lab vs. 38% in a hybrid operating room. Major bleeding and infections were higher in the hybrid OR group. Midterm mortality was similar between the catheterization lab and the hybrid operating room; therefore, findings supported performance in either location.[4]

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Policy Revision History/Information

Original Date: April 12, 2024		
Review History		
Version 1	04/12/2024	New policy.
Version 2	08/13/2024	Updated indications, non-indications, and references.
Version 3	08/14/2025	Annual review. Added a new Description section. Language was revised for clarity. Additional citations were added throughout the indications section. Medical Evidence - added two new reviews.