Transcatheter Aortic Valve Replacement (TAVR) - Single Service

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Transcatheter Aortic Valve Replacement (TAVR) (Single Service)

Literature review current through: 4/12/2024
Document last updated: 4/12/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17yo)

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Service: Transcatheter Aortic Valve Replacement/Implantation (TAVR)

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** Dysfunction of previous TAVR.
- **Recommended Clinical Approach:** TAVR is an effective catheter-based procedure for the treatment of aortic stenosis. Patients considered for TAVR 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] TAVR valves are durable for at least 5 years.[1] The Society of Thoracic Surgeons estimated surgical risk score provides a useful measure of the extent of patient comorbidities and may help identify which patients will benefit from TAVR.[1]
- **Exclusions:** Life expectancy less than 1 year despite a successful procedure or those with a chance of "survival with benefit" of less than 25% at 2 years.[1, 7-8]

Medical Necessity Criteria

Indications

➔ **TAVR** is considered appropriate if **ANY** of the following is **TRUE**[1-8]:

- For patients with symptomatic severe aortic stenosis; **OR**
- For asymptomatic patients with severe aortic stenosis and left ventricular dysfunction (LVEF less than 50%); **OR**
- For patients with asymptomatic severe aortic stenosis and low surgical risk when an exercise test demonstrates **ANY** of the following:
  - Decreased exercise tolerance (normalized for age and sex); **OR**
  - A fall in systolic blood pressure of greater than or equal to 10 mm Hg from baseline to peak exercise; **OR**
- For asymptomatic patients with very severe AS (defined as an aortic velocity of greater than or equal to 5 m/s) and low surgical risk; **OR**
- For patients with symptomatic aortic stenosis with low-flow/ low-gradient severe aortic stenosis; **OR**

- For valve-in-valve procedures for failed prior bioprosthetic valves, including **ANY** of the following[1,3-6]:
  - The patient has a bioprosthetic aortic valve with aortic stenosis, and **ALL** of the following are **TRUE**:
    - The patient has symptomatic (e.g., fatigue, dyspnea, angina, syncope, or presyncope) severe stenosis; **AND**
    - Improvement in hemodynamics is anticipated; **OR**
  - The patient has a bioprosthetic aortic valve with aortic regurgitation, and **ALL** of the following are **TRUE**:
    - The patient has symptomatic (e.g., dyspnea, orthopnea) severe regurgitation; **AND**
    - Improvement in hemodynamics is anticipated.

Non-Indications

➔ **TAVR** may not be considered appropriate if **ANY** of the following is **TRUE**[2,5-8]:

- Life expectancy less than 12 months related to a non-cardiac cause; **OR**
- Myocardial infarction within the last thirty days; **OR**
- Congenital unicuspid valve, bicuspid valve with unsuitable anatomy for TAVR, or noncalcified valve; **OR**
- Hypertrophic obstructive cardiomyopathy; **OR**
- A short distance between the annulus and coronary ostium for an artery unprotected by a bypass graft and concern that TAVR may result in coronary obstruction that cannot be protected; **OR**
- Left ventricular ejection fraction less than 20%; **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; **OR**
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation(unless completely healed); **OR**
- Severe primary mitral regurgitation without a plan to perform a transcatheter MitraClip procedure after TAVR; **OR**
- Severe functional mitral regurgitation determined unlikely to improve after TAVR or without a plan to perform a transcatheter MitraClip procedure after TAVR; **OR**

- MRI confirmed stroke or transient ischemic attack (TIA) within the last six months unless the heart team determines that the risk of delaying treatment of aortic stenosis exceeds the potential benefit from delaying TAVR; **OR**
- Mixed aortic valve disease (concomitant aortic regurgitation) if there is determined to be inadequate valve calcification to allow TAVR; **OR**
- A significant aortoiliac disease that would interfere with delivery and deployment of the stent-valve without alternative access approach available (transcarotid, transaxillary, transapical or transcaval)[3-6]; **OR**
- The patient is unable to tolerate an anticoagulation/antiplatelet regimen[7]; **OR**
- Allergy or sensitivity to titanium or nickel.[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

Otto et al. (2020) developed a guideline for the American College of Cardiology and the American Heart Association for the management of 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 need for longer valve durability. In patients older than age 65, TAVR presents less surgical risk, pain and length of hospital stay compared to SAVR, while SAVR is associated with 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 vs. 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 vs. 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. 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 found to be higher in the hybrid OR groupMidterm mortality was found to be similar between the catheterization lab and the hybrid operating room; therefore findings supported performance in either location.[4]

References

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2. American College of Radiology. ACR manual on contrast media. https://www.acr.org/-/media/ACR/files/clinical-resources/contrast_media.pdf
3. Chen S, Redfors B, Ben-Yehuda O, et al. Transcatheter versus surgical aortic valve replacement in patients with prior cardiac surgery in the randomized PARTNER 2A trial. *JACC Cardiovasc Interv*. 2018;11(21):2207-2216.
4. Spaziano M, Lefèvre T, Romano M, et al. Transcatheter aortic valve replacement in the catheterization laboratory versus hybrid operating room: insights from the FRANCE TAVI registry. *JACC Cardiovasc Interv*. 2018; 11(21):2195-2203.
5. Chetcuti SJ, Deeb GM, Popma JJ, et al. Self-expanding transcatheter aortic valve replacement in patients with low-gradient aortic stenosis. *JACC Cardiovasc Imaging*. 2019;12(1):67-80.
6. Egger F, Zweiker D, Freynhofer MK, et al. Austrian TAVI Group. Impact of on-site cardiac surgery on clinical outcomes after transfemoral transcatheter aortic valve replacement. *JACC Cardiovasc Interv*. 2018;11(21):2160-2167.
7. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Edwards Sapien 3 transcatheter heart valve. Published August 16, 2019. https://www.fda.gov.
8. US Food & Drug Administration (FDA). Summary of safety and effectiveness data: Medtronic CoreValve system. Published July 10, 2017. https://www.fda.gov.

Clinical Guideline Revision History/Information

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