

Molina Clinical Policy

Transcatheter Aortic Valve Replacement for Aortic Valve Disease: Policy No. 175

Last Approval: 8/10/2022

Next Review Due By: August 2023



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Aortic stenosis (AS) is the narrowing of the aortic valve, which obstructs the blood flow from the left ventricle of the heart to the ascending aorta. Stenosis can occur because of thickening, stiffening, or fusion of the aortic valve, which prevents the valve from opening completely and limits the amount of blood flowing through the valve. Aortic stenosis can be congenital or acquired. The most common cause of aortic stenosis in the elderly is aortic sclerosis, a degenerative disease characterized by fibrosis and calcification of the aortic valve. In patients who are less than 70 years of age, the most common cause of aortic stenosis is a congenital bicuspid aortic valve. Rheumatic fever is the most common cause of aortic stenosis in developing countries. Other potential causes of aortic valve disease include autoimmune disorders, carcinoid syndrome, metabolic disorders, weight-loss medications, and radiation therapy. Individuals who have a history of infective endocarditis, myocardial infarction, or heart failure are at an increased risk of developing aortic stenosis. Other risk factors include old age, hypercholesterolemia, hypertension, diabetes, insulin resistance, obesity, smoking, and a family history of early cardiac disease. (Brecker, et al., 2022; Pellikka, 2022; Brecker, 2021; MCG, 2021; AMR, 2020; CMS, 2019; Hayes, 2018; Hayes, 2017).

AS is graded on a combination of hemodynamic and natural history data. According to current guidelines, severe AS is defined as an aortic valve area (AVA) $<1.0 \text{ cm}^2$ (or $<0.6 \text{ cm}^2/\text{m}^2$ body surface area), mean aortic valve pressure gradient $>40 \text{ mm Hg}$, or an aortic jet velocity $>4 \text{ m/s}$. Two-dimensional transthoracic echocardiography (TTE) is the standard for diagnosis and severity assessment through Doppler quantification of maximum jet velocity, mean transvalvular pressure gradient, and AVA by continuity equation. (FDA, 2020).

Transcatheter aortic valve replacement also referred to as percutaneous or catheter-based aortic valve replacement or percutaneous aortic valve implantation, is a minimally invasive heart surgery that involves the positioning and placement of the aortic valve prosthesis via a catheter inserted into a vein. These techniques allow cardiopulmonary bypass to be avoided and may reduce the risks of bleeding and infection. (Brecker, et al., 2022; Pellikka, 2022; Brecker, 2021; MCG, 2021; AMR, 2020; Hayes, 2018; Hayes, 2017).

The transcatheter procedures used to deploy and set replacement aortic valves into place can be transfemoral or transapical or, less commonly, subclavian or direct transaortic access. The transfemoral procedure involves inserting a flexible aortic valve prosthetic device into a catheter, threading the catheter up the femoral vein and into the heart, where the valve is released and set into place. The transapical procedure involves a small incision being made into the chest and then the catheter is fed through the apex (tip) of the heart where the valve is released and set into place. A balloon may be used to expand the valve while seating it into its proper position in any of the procedures. Complications of transcatheter aortic valve replacement (TAVR) include shock and low cardiac output during and following deployment, annular rupture, vascular complications, myocardial injury, heart block, paravalvular aortic regurgitation, and stroke. (Brecker, et al., 2022; Pellikka, 2022; Brecker, 2021; MCG, 2021; Hayes, 2018; Hayes, 2017).

The FDA classifies transcatheter aortic valve implantation (TAVI) devices as Class III under the designation "aortic valve, prosthesis, percutaneously delivered" (premarket approval [PMA] Product Code NPT). Currently, three companies have products approved for marketing in the United States: Boston Scientific, Edwards Lifesciences and Medtronic Inc. Boston Scientific markets the LOTUS aortic valve system, Edwards Lifesciences markets the following

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three FDA approved valves: SAPIEN, SAPIEN XT, and SAPIEN 3. The Edwards SAPIEN devices are a balloon-expandable stainless-steel frame that supports a valve created from bovine pericardial tissue. Medtronic Inc. markets the FDA approved CoreValve System. The CoreValve device is a self-expandable nitinol frame that supports a valve created from porcine pericardial tissue. (¹⁻² FDA, 2021; FDA, 2020; FDA, 2019; FDA, 2017; FDA, 2015; FDA, 2011).

The Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for *Transcatheter Aortic Valve Replacement (TAVR)* (20.32) states that CMS covers TAVR for the treatment of symptomatic aortic valve stenosis when furnished according to an FDA approved indication and when all of the conditions are met: (CMS, 2019).

1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.
2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team includes the following:
 - a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
 - independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
 - documented and made available to the other heart team members the rationale for their clinical judgment.
 - b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.
3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

COVERAGE POLICY

Transcatheter aortic valve implantation using an FDA approved valve **may be considered medically necessary** in children and adults when **ALL** the following criteria are met: (MCG, 2021; AMR, 2020; CMS, 2019; Holmes et al., 2012)

1. Evaluation by an experienced heart team that includes a cardiologist and/or cardiac interventionalist and cardiothoracic surgeons experienced in the care and treatment of aortic stenosis who have:
 - a. Independently examined the patient face-to-face; **AND**
 - b. Evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy; **AND**
 - c. Documented and made available to the other heart team members the rationale for their clinical judgment.

AND

2. Diagnosis of aortic valve disease requiring treatment as indicated by **1 or more** of the following:
 - a. Symptomatic (e.g., fatigue, dyspnea, angina, syncope, or presyncope by history or on exercise testing) severe high-gradient aortic stenosis (peak transaortic Doppler velocity greater than or equal to 4.0 m/sec or mean transaortic pressure gradient greater than or equal to 40 mm Hg); **OR**
 - b. Symptomatic (e.g., fatigue, heart failure, angina, syncope, or presyncope) severe low-gradient aortic stenosis (valve area less than or equal to 1.0 cm² with resting peak transaortic Doppler velocity less than 4.0 m/sec or mean transaortic pressure gradient less than 40 mm Hg) and **1 or more** of the following:
 - Left ventricular ejection fraction less than 50% and low dose dobutamine stress study shows peak transaortic velocity greater than or equal to 4.0 m/sec or mean transaortic pressure gradient greater than or equal to 40 mm Hg; **AND**
 - Administer appropriate recommended dobutamine infusion dosing (2.5-20 mcg/kg/min) to avoid high dose pressors overestimating outflow velocity; **OR**
 - Symptoms believed to be due to valve disease, with resting valve area index less than 0.6 cm²/m² body surface area and stroke volume index less than 35 mL/m².

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OR

- c. Bioprosthetic aortic valve with aortic stenosis as indicated by **ALL** of the following:
- Severe symptoms (e.g., fatigue, dyspnea, angina, syncope, or presyncope); **AND**
 - Improvement in hemodynamics anticipated.

OR

- d. Bioprosthetic aortic valve with aortic regurgitation as indicated by **ALL** of the following:
- Severe symptoms (e.g., dyspnea, orthopnea); **AND**
 - Improvement in hemodynamics anticipated.

OR

- e. Anatomy is suitable for the transcatheter valve procedure.

Limitations and Exclusions

(Otto et al, 2021; Adams et al., 2014; Nishimura, et al., 2014; Holmes et al., 2012).

Exclusions include presence of any of the following conditions:

1. Evidence of an acute myocardial infarction ≤ 1 month (30 days) before the intended treatment.
2. Hemodynamic or respiratory instability requiring inotropic support, mechanical ventilation, or mechanical heart assistance within 30 days of screening evaluation.
3. Hypertrophic cardiomyopathy with or without obstruction.
4. Severe left ventricular dysfunction with LVEF $< 20\%$.
5. Severe pulmonary hypertension and RV dysfunction.
6. Echocardiographic evidence of intracardiac mass, thrombus or vegetation.
7. A known contraindication or hypersensitivity to all anticoagulation regimens, or inability to be anticoagulated for the study procedure.
8. MRI confirmed CVA or TIA within 6 months (180 days) of the procedure.
9. Renal insufficiency (creatinine > 3.0 mg/dL) and/or end-stage renal disease requiring chronic dialysis at the time of screening.
10. Estimated life expectancy < 12 months (365 days) due to noncardiac comorbid conditions.
11. Severe incapacitating dementia.
12. Severe mitral regurgitation.
13. Significant aortic disease:
 - Thoracic or abdominal aortic aneurysm (luminal diameter ≥ 5 cm), marked tortuosity (hyperacute bend);
 - Aortic arch atheroma (especially if > 5 mm thick, protruding, or ulcerated);
 - Narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta;
 - Marked tortuosity (hyperacute bend) of the aorta or severe “unfolding” of the thoracic aorta.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The preponderance of peer reviewed medical evidence for TAVI for aortic stenosis is of low to moderate in quality. There are randomized controlled trials (RCTs), but the majority of the literature regarding TAVI consists of case series. One RCT was comprised of two cohorts of the Placement of Aortic Transcatheter Valves (PARTNER) trial. Cohort A compared TAVI with SAVR (Bavaria et al., 2019; Aortic Stenosis Writing Group, et al., 2018; Adams et al., 2014) and cohort B compared TAVI with standard medical management (Barbanti, et al., 2019; Baron et al., 2019). A sixth study

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examined vascular complications that occurred following TAVI in both cohorts. In both cohorts, TAVI was performed using the Edwards SAPIEN system. In cohort A, there were no differences in mortality and symptoms between patients in the TAVI and SAVR groups at any time points, with the exception of NYHA class, which showed greater improvement in the TAVI group at 30-days post-intervention. At one month following surgery, QOL in the patients receiving TAVI via the transfemoral route was significantly improved relative to the SAVR group; however, this difference disappeared by the 6-month follow-up (Adams et al., 2014). In cohort B, TAVI was associated with a significant reduction in mortality and improvement of symptoms at 1 and 2 years after intervention, compared with standard treatment. At 2 years, patients in the TAVI group had significantly more days alive and out of the hospital compared with patients in the medical management group. Five-year outcomes showed that TAVR is more beneficial than standard treatment for treatment of inoperable aortic stenosis. TAVR should be strongly considered for patients who are not surgical candidates for aortic valve replacement to improve their survival and functional status (Carrabba et al., 2013).

The overall quality of evidence evaluating the comparative effectiveness and safety of TAVI versus SAVR was rated as moderate for both low-risk patients and intermediate-risk patients. Two large multicenter randomized controlled trials comparing SAVR and TAVR in low-risk patients have been published (Fu et al., 2019; Doshi et al., 2018). The first study of 1000 patients randomized patients to SAVR or TAVR and found that for the primary composite outcome of death, stroke, or rehospitalization at one-year TAVR was noninferior and superior. In prespecified secondary endpoints, at 30 days TAVR resulted in lower rates of stroke (0.6% vs 2.4%), death or stroke (1% vs 3.3%), and new-onset atrial fibrillation (5% vs 40%), while safety outcomes were similar (e.g., major vascular outcomes and permanent pacemaker insertion). In terms of echocardiographic outcomes, at 30 days the mean aortic valve gradient and area were similar, as was the rate of moderate to severe paravalvular regurgitation at 30 days and 1 year (Doshi et al., 2018). The second study of 1403 low-risk patients with severe aortic stenosis randomized to TAVR or SAVR found TAVR to be noninferior to SAVR for the composite endpoint of death or disabling stroke estimated at 24 months (5.3% vs 6.7%), with lower 30-day incidence of disabling stroke, bleeding complications, acute kidney injury, and atrial fibrillation; however, the TAVR group had a higher rate of post-procedure aortic regurgitation and higher need for pacemaker insertion (Fu et al., 2019).

National and Specialty Organizations

The American College of Cardiology (ACC) published the *2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults with Aortic Stenosis*. The publication builds on the recommendations found in the *2014 ACC/American Heart Association Guidelines for Management of Patients with Valvular Heart Disease* (see below). Highlights include treatment of native valve aortic stenosis; it does not address “valve-in-valve” procedures and includes point-of-care checklists for the following: TAVR patient selection and evaluation, TAVR imaging assessment, TAVR procedure (key issues and considerations in performing the procedure and managing complications), and post-TAVR clinical management (Otto et al., 2017).

In 2021, the ACC published the *2020 ACC Expert Consensus Decision Pathway on Management of Conduction Disturbances in Patients Undergoing Transcatheter Aortic Valve Replacement* (Lilly et al., 2021). The document discussed relevant data and experience regarding the management of conduction disturbances after TAVR. In addition, an evidence-based expert consensus decision pathway is proposed to provide a framework for the risk assessment and management of rhythm disturbances after TAVR.

In 2014, the **American Heart Association (AHA) / American College of Cardiology (ACC)** published the *AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease*. Specific recommendations for the use of TAVI include that a heart team, consisting of an integrated, multidisciplinary group of healthcare professionals with expertise in valvular heart diseases, cardiac imaging, interventional cardiology, cardiac anesthesia, and cardiac surgery, should collaborate to provide optimum care. TAVI is recommended for patients who meet an indication for SAVR with prohibitive risk for SAVR and postoperative survival > 12 months. TAVI is a reasonable alternative to SAVR in patients at high surgical risk. TAVI is not recommended for patients with comorbidities that preclude the benefit from correction of AS (Reardon et al., 2017). These guidelines support valve-in-valve TAVR for severely symptomatic patients with either bioprosthetic aortic valve stenosis or bioprosthetic aortic valve regurgitation when hemodynamic improvement is anticipated and when judged by a heart team to be at high or prohibitive risk for surgical therapy. (Otto et al., 2021; Nishimura, et al., 2017; Nishimura, et al., 2014).

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In 2021, the ACC/AHA published the *Guideline for the Management of Patients with Valvular Heart Disease*. Recommendations for the evaluation and management of VHD continue to be based on clinical experience and observational studies, with prospective RCTs limited mostly to new devices. The guideline recommends that research on valve disease span the spectrum from basic science to prospective randomized trials – research should include medical therapy and studies should focus on each stage of the disease process (e.g., from the patient at risk to the patient with end-stage disease). (Otto et al., 2021).

The Society for Cardiovascular Angiography and Interventions (SCAI), American Association for Thoracic Surgery (AATS), American College of Cardiology Foundation (ACCF), and the Society of Thoracic Surgeons (STS) issued a joint expert consensus statement which indicates that transcatheter aortic valve replacement (TAVR) is recommended in patients with severe, symptomatic, calcific stenosis of a trileaflet aortic valve who have aortic and vascular anatomy suitable for TAVR and a predicted survival >12 months, and who have a prohibitive surgical risk as defined by an estimated 50% or greater risk of mortality or irreversible morbidity at 30 days or other factors such as frailty, prior radiation therapy, porcelain aorta, and severe hepatic or pulmonary disease. (Holmes et al., 2012).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	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 (e.g., median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., 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 (e.g., 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 (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

HCPCS Codes – N/A

ICD-10 Codes

ICD-10	Description
I06.0	Rheumatic aortic stenosis
I06.2	Rheumatic aortic stenosis with insufficiency
I08.0-I08.9	Rheumatic disorders of both mitral and aortic valves (excluding I08.1)
I35	Nonrheumatic aortic valve disorders
I35.0	Aortic (valve) stenosis

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I35.2	Aortic (valve) stenosis with insufficiency
Q23.0	Congenital stenosis of aortic valve

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/10/2022	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
8/11/2021	Policy reviewed, no updates.
6/17/2020	Policy reviewed and clinical criteria changed based on new literature and guidelines. CMS NCD for Transcatheter Aortic Valve Replacement (TAVR) (20.32) section was updated (effective 6/21/2019, implemented 6/12/2020). Medical necessity criteria now includes high and low gradient aortic stenosis, and bioprosthetic aortic valve with aortic stenosis or regurgitation. FDA approved valve devices section was updated. References updated.
6/19/2019	Policy reviewed, no changes; updated guidelines and references.
7/10/2018	Policy reviewed, no changes; updated guidelines and references.
6/5/2017	Policy reviewed, no changes to clinical criteria. Updated Summary of Medical Evidence and References.
6/16/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
7/10/2014	New policy.

REFERENCES

Government Agencies

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- ¹ United States Food and Drug Administration (FDA). Boston Scientific announces LOTUS Edge™ aortic valve system voluntary recall and product discontinuation. Available from [FDA](#). Published January 11, 2021. Accessed July 11, 2022.
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Evidence Based Reviews and Publications

- AMR Peer Review. Policy reviewed in May 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Cardiovascular Disease, Interventional Cardiology, Internal Medicine.
- Brecker S, Aldea GS. Choice of intervention for severe calcific aortic stenosis. Available from [UpToDate](#). Updated June 15, 2022. Accessed July 12, 2022. Registration and login required.
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- MCG. Inpatient and surgical care: Aortic valve replacement, transcatheter, 25th ed. (ORG: S-1320 [ISC]). Available from [MCG](#). Published June 7, 2021. Accessed July 12, 2022. Registration and login required.
- Pellikka PA. Indications for valve replacement for high gradient aortic stenosis in adults. Available from [UpToDate](#). Updated June 16, 2022. Accessed July 12, 2022. Registration and login required.

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National and Specialty Organizations

1. Aortic Stenosis Writing Group, Bonow RO, Brown AS, Gillam LD, Kapadia SR, Kavinsky CJ, et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/ SCCT/SCMR/STS 2017 appropriate use criteria for the treatment of patients with severe aortic stenosis: A Report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. J Am Soc Echocardiogr. 2018 Feb;31(2):117-147. doi: 10.1016/j.echo.2017.10.020. Accessed July 12, 2022.
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*NOTE: Policy reviewed in May 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physicians in the areas of Cardiovascular Disease, Interventional Cardiology, Internal Medicine.

APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.