Subject: Transcatheter Aortic Valve Replacement for Aortic Valve Disease		Original Effective Date: 7/10/2014
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members. [1]

DESCRIPTION OF PROCEDURE [5 28]

Aortic Stenosis

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.

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 cm2 (or <0.6 cm2/m2 body surface area), mean aortic valve pressure gradient >40 mm Hg, or an aortic jet velocity >4 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. [5]

Transcatheter aortic valve replacement

Transcatheter pulmonary 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.

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.

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 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. [2]

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) [1]

The National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) #20.32 (Effective date 6/21/19 & implemented 6/12/20) 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 following conditions are met: [1]

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:
    i. independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
    ii. 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.

INITIAL COVERAGE CRITERIA 3-8-9-40 46

Transcatheter aortic valve implantation using an FDA approved valve may be considered medically necessary in children and adults when the following criteria are met: [ALL]

- ❑ 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:
    - o independently examined the patient face-to-face; and
    - o evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy; and
    - o documented and made available to the other heart team members the rationale for their clinical judgment; and

- ❑ Diagnosis of aortic valve disease requiring treatment as indicated by **1 or more** of the following:
    - o Symptomatic (ie, 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
    - o Symptomatic (ie, fatigue, heart failure, angina, syncope, or presyncope) severe low-gradient aortic stenosis (valve area less than or equal to 1.0 cm^2 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 cm^2/m^2 body surface area and stroke volume index less than 35 mL/m^2
    - o Bioprosthetic aortic valve with aortic stenosis as indicated by **ALL** of the following:
        - Severe symptoms (ie, fatigue, dyspnea, angina, syncope, or presyncope); and
        - Improvement in hemodynamics anticipated; and

- Bioprosthetic aortic valve with aortic regurgitation as indicated by **ALL** of the following:
  - Severe symptoms (eg, dyspnea, orthopnea); and
  - Improvement in hemodynamics anticipated; and

- Anatomy is suitable for the transcatheter valve procedure

EXCLUSIONS [3 4 5 28 29]

Exclusions include presence of any of the following conditions:

- ❑ Evidence of an acute myocardial infarction ≤1 month (30 days) before the intended treatment
- ❑ Hemodynamic or respiratory instability requiring inotropic support, mechanical ventilation, or mechanical heart assistance within 30 days of screening evaluation
- ❑ Hypertrophic cardiomyopathy with or without obstruction
- ❑ Severe left ventricular dysfunction with LVEF <20%
- ❑ Severe pulmonary hypertension and RV dysfunction
- ❑ Echocardiographic evidence of intracardiac mass, thrombus or vegetation
- ❑ A known contraindication or hypersensitivity to all anticoagulation regimens, or inability to be anticoagulated for the study procedure
- ❑ MRI confirmed CVA or TIA within 6 months (180 days) of the procedure
- ❑ Renal insufficiency (creatinine >3.0 mg/dL) and/or end-stage renal disease requiring chronic dialysis at the time of screening
- ❑ Estimated life expectancy <12 months (365 days) due to noncardiac comorbid conditions
- ❑ Severe incapacitating dementia
- ❑ Severe mitral regurgitation
- ❑ 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

SUMMARY OF MEDICAL EVIDENCE [7-40]

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, [7 8 9] and cohort B compared TAVI with standard medical management. [10 11] A sixth study examined vascular complications that occurred following TAVI in both cohorts. [12] 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. [9] 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. [19]

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. [35] [36] 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 1 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 (eg, 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. [35] 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 postprocedure aortic regurgitation and higher need for pacemaker insertion. [36]

Professional Organizations [3-6]

2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults with Aortic Stenosis: Continues to build on the recommendations found in the 2014 ACC/American Heart Association Guidelines for Management of Patients with Valvular Heart Disease. This document focuses on 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. [3a]

2014 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. [3b]
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. [3b]

Society for Cardiovascular Angiography and Interventions (SCAI), American Association for Thoracic Surgery (AATS), American College of Cardiology Foundation (ACCF), Society of Thoracic Surgeons (STS: In a joint expert consensus statement the SCAI, AATS, ACCF, and STS indicate 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. [3d]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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 (eg, 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 (eg, 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 (eg, 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 (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
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
I35.2	Aortic (valve) stenosis with insufficiency
Q23.0	Congenital stenosis of aortic valve

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Review/Revision History:

7/10/14: Policy created
12/16/15 & 6/16/16: Policy reviewed, no changes
6/5/17: The policy was reviewed and the clinical criteria section did not change. The following sections were updated: Summary of medical evidence, professional guidelines and references.
7/10/18 & 6/19/19: Policy reviewed, no changes, updated guidelines and references.
6/17/20: Policy reviewed and clinical criteria changed based on new literature and guidelines. The CMS National Coverage Determination for Transcatheter Aortic Valve Replacement (TAVR) (20.32) section was updated with new criteria effective 6/21/19 & implemented 6/12/20. The medical necessity criteria was updated to include high and low gradient aortic stenosis, and bioprosthetic aortic valve with aortic stenosis or regurgitation. FDA approved valve devices section was updated. References and guidelines were updated.