Subject: Transcatheter Aortic Valve Replacement for Aortic Stenosis	Original Effective Date: 7/10/14
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PREFACE

This Medical Guidance 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 exclusions 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 following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

Transcatheter aortic valve replacement is a procedure and, therefore, not subject to FDA regulation. The FDA classifies transcatheter aortic valve implantation (TAVI) devices as Class III under the designation "aortic valve, prosthesis, percutaneously delivered" (PMA product code NPT). The Edwards SAPIEN Transcatheter Heart Valve (Edwards Lifesciences LLC) was approved on November 2, 2011, for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis. The SAPIEN Transcatheter Heart Valve is indicated for patients with severe symptomatic native aortic valve stenosis, who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis. [1]

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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 medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

The 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 following conditions are met: [2]

- 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.
- Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open AVR surgery, both surgeons have documented the rationale for their clinical judgment, and the rationale is available to the heart team.

- Patient (preoperatively and postoperatively) is under the care of a heart team that is 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.

INITIAL COVERAGE CRITERIA [4 6 13]

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

- ❑ Evaluation by an experienced heart team that includes a cardiologist and/or cardiac interventionalist and two cardiothoracic surgeons who have documented that either:
  - open surgical AVR is inoperable and existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis; or
  - open surgical AVR candidate with a Society of Thoracic Surgeons predicted operative risk score ≥ 8%, or are judged by the heart team to be at a ≥ 15% risk of mortality for surgical aortic valve replacement

- ❑ Diagnosis of calcific aortic valve stenosis confirmed by echocardiograph as:
  - mean gradient >40 mm Hg or jet velocity >4.0 m/s; or
  - initial Aortic Valve area (AVA) of <0.8 cm^2 or indexed effective orifice area (EOA) <0.5 cm^2/m^2 within 45 days of the date of the procedure; and
  - symptomatic of aortic valve stenosis (i.e. angina, syncope, progressive exercise intolerance); and
  - NYHA functional class II or greater; and
  - Ejection fraction > 20%

COVERAGE EXCLUSIONS [4 6 13]

Coverage exclusions include presence of any of the following conditions:

- ❑ Evidence of an acute myocardial infarction ≤1 month (30 days) before the intended treatment
- ❑ Aortic valve is a congenital unicuspid or congenital bicuspid valve, or is noncalcified
- ❑ 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

DESCRIPTION OF PROCEDURE

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. [6]

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. [3]

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. [3] [6] 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. [14-18]

SAPIEN Valve

The Edwards SAPIEN device is a balloon-expandable stainless steel frame that supports a valve created from bovine pericardial tissue and is available in 23- and 26-millimeter (mm) sizes.

GENERAL INFORMATION

Summary of Medical Evidence

The preponderance of peer reviewed medical evidence for TAVI for aortic stenosis is of low to moderate in quality. There was one randomized controlled trial (RCT), but the majority of the literature regarding TAVI consists of case series. The only 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.

Hayes published a medical directory report for TAVI in aortic stenosis that outlines sufficient evidence to support the use of TAVI in patients with severe aortic stenosis who are not candidates for conventional SAVR because of significant comorbid conditions, porcelain aorta, or frailty. [3]

Professional Organizations

American College of Cardiology (ACC): The ACC, in collaboration with the STS, AATS, and SCAI, released an expert consensus document (2012) to provide important guidance on the use of TAVI. The consensus document outlines the following key recommendations for the successful employment of TAVI: [5]

- Careful patient selection.
- Team-based approach given the complexity of TAVI coupled with the high-risk profile of suitable patients, many of whom have extensive comorbid conditions that require ongoing management.

- Specialized heart centers and physicians with expertise in treating valve disorders; this includes use of proctors as needed to serve on the heart care team during the first few cases, as well as proper facilities (hybrid operating rooms or modified catheterization laboratories).
- TAVI screening tests to inform treatment decisions.
- Enhanced patient and family education in the risk and benefits of this procedure.
- Ongoing evaluation and participation in national TAVI registry to assess real-world outcomes.

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. [4]

The California Technology Assessment Forum and the National Institute for Health and Clinical Excellence (NICE) have published guidelines for transcatheter aortic valve implantation (TAVI) for aortic stenosis as a treatment for patients with severe symptomatic AS with unacceptably high risk for surgical aortic valve replacement . [20-21]

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)
0318T	Implantation of catheter-delivered prosthetic aortic heart valve, open thoracic approach, (eg, transapical, other

	than transaortic)

HCPCS	Description
	N/A

ICD-9	Description
424.1	aortic valve disorders (used for nonrheumatic disorders)
395.0	rheumatic aortic stenosis
395.2	rheumatic aortic stenosis with insufficiency
396.0	mitral valve stenosis and aortic valve stenosis
396.2	mitral valve insufficiency and aortic valve stenosis
396.8	multiple involvement of mitral and aortic valves
746.3	congenital stenosis of aortic valve
746.81	subaortic stenosis, congenital
747.22	congenital atresia and stenosis of aorta
996.02	Mechanical complication of cardiac device, implant and graft, due to heart valve prosthesis
996.71	Other complications of internal (biological) (synthetic) prosthetic device, implant and graft; due to heart valve prosthesis
V43.3	Organ or tissue replaced by other means; heart valve

ICD-10	Description
I06.0	rheumatic aortic stenosis
I06.2	rheumatic aortic stenosis with insufficiency
I08.0	disorders of both mitral and aortic valves
I35	nonrheumatic aortic valve disorders
I35.0	aortic (valve) stenosis
I35.2	aortic (valve) stenosis with insufficiency
I35.8	other aortic valve disorders
I35.9	aortic valve disorder, unspecified
I39.1	aortic valve disorders in diseases classified elsewhere

Q23.0	congenital stenosis of aortic valve
Q24.4	congenital subaortic stenosis
Q25	congenital malformations of great arteries
Q25.2	atresia of aorta
Q25.3	stenosis of aorta
T82.01XA-T82.09XA	Breakdown (mechanical) of heart valve prosthesis; Other mechanical complication of heart valve prosthesis, initial encounter
T82.87A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter
Z95.2	Presence of prosthetic heart valve

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