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MEDICAL POLICY – 7.01.132

Transcatheter Aortic-Valve Implantation for Aortic Stenosis

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

The aortic valve is a valve that separates the main pumping chamber of the heart (the left ventricle) from the large artery that takes oxygen rich blood away from the heart and out to the body (the aorta). If the valve doesn't completely open, it is called aortic stenosis. Aortic stenosis decreases the amount of oxygenated blood getting out to the body. Open surgery is one method of replacing a damaged aortic valve. A newer procedure — known as transcatheter aortic valve replacement or transcatheter aortic valve implantation — has been developed. It allows a replacement valve to be threaded through an artery and into the heart without open heart surgery. A catheter (a long thin, tube) is threaded through an artery, either in the leg or in the chest, and into the heart. The replacement valve is then lodged into the defective aortic valve. The new valve is then expanded, pushing aside parts of the old valve. This policy describes when transcatheter aortic valve replacement may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Medical Necessity
Transcatheter aortic valve replacement	**Transcatheter aortic valve replacement with an FDA–approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling, may be considered medically necessary for individuals with native valve aortic stenosis when ALL of the following conditions are present:** • Severe aortic stenosis (see the **Definition of Terms** section) with a calcified aortic valve **AND** • New York Heart Association (NYHA) heart failure class II, III, or IV symptoms (see the **Definition of Terms** section) **AND** • Individual does not have unicuspid or bicuspid aortic valves **Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) may be considered medically necessary when ALL of the following conditions are present:** • Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve **AND** • New York Heart Association heart failure class II, III, or IV symptoms (see the **Definition of Terms** section) **AND** • Individual is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon) **OR** • Individual is an operable candidate but is considered at increased surgical risk for open surgery, as documented by at least 2 cardiac specialists (including a cardiac surgeon) **OR**

Procedure	Medical Necessity
	• Individual is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies **and/or** has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon) (see the **Definition of Terms** section) **Transcatheter aortic valve replacement is considered investigational for all other indications and when above criteria are not met.**

Procedure	Investigational
Cerebral embolic protection devices	**Use of a cerebral embolic protection device (e.g., Sentinel) during transcatheter aortic valve replacement procedures is considered investigational**

Documentation Requirements
The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition • History and physical examination documenting the severity of the condition • NYHA heart failure class symptoms • Individual is at high risk for open surgery or is not an operable candidate for open surgery (see **Definition of Terms** below) • Whether transcatheter heart valve system is FDA approved and will be used in a manner consistent with FDA labeling

Coding

Code	Description
CPT	
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach

Code	Description
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)
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)
HCPCS	
C1884	Embolization protective system

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

Extreme risk or inoperable for open heart surgery: The US Food and Drug Administration (FDA) definition of extreme risk or inoperable for open surgery is:

- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery

High risk for open heart surgery: FDA definition of high risk for open surgery is:

- Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery

Intermediate risk: FDA definition of intermediate risk is:

- Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.

Individuals with Society of Thoracic Surgeons predicted operative risk score of less than 3% or 4% are considered at low risk for open surgery.

Some individuals being considered for valve-in-valve transcatheter aortic valve replacement may be deemed at increased surgical risk for open surgery despite low-to-moderate STS risk scores. This may include individuals with advanced age, complex intrathoracic histories, congenital cardiac anomalies, liver disease, or other extreme comorbid conditions not accurately captured by STS risk scores as documented by at least 2 cardiovascular specialists, including a cardiac surgeon.[1,2]

Severe aortic stenosis: For the use of the SAPIEN or CoreValve devices, severe aortic stenosis is defined by the presence of one or more of the following criteria:

- An aortic valve area of less than or equal to 1 cm^2
- An aortic valve area index of less than or equal to 0.6 cm^2/m^2
- A mean aortic valve gradient greater than or equal to 40 mm Hg
- A peak aortic-jet velocity greater than or equal to 4.0 m/s

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.

Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Evidence Review

Description

Aortic stenosis is narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Individuals with untreated, symptomatic severe aortic stenosis have a poor prognosis. Valve replacement is an effective treatment for severe aortic stenosis. Transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement [TAVR]) is being evaluated as an alternative to open surgery for individuals with aortic stenosis and to nonsurgical therapy for individuals with a prohibitive risk for surgery.

Background

Aortic Stenosis

Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries.[3] Congenital abnormalities of the aortic valve, most commonly a bicuspid or unicuspid valve, increase the risk of aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia.[3] Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis (i.e., deposition of atherogenic lipids and infiltration of inflammatory cells, followed by progressive calcification).

The natural history of aortic stenosis involves a long asymptomatic period, with slowly progressive narrowing of the valve until the stenosis reaches the severe stage. At this time, symptoms of dyspnea, chest pain, and/or dizziness/syncope often occur, and the disorder progresses rapidly. Treatment of aortic stenosis is replacement of the diseased valve with a bioprosthetic or mechanical valve.

Disease Burden

Aortic stenosis is a relatively common disorder in elderly individuals and is the most common acquired valve disorder in the United States. Approximately 2% to 4% of people older than 65 years of age have evidence of significant aortic stenosis,[3] increasing up to 8% of people by age 85 years.[4] In the Helsinki Aging Study (1993), a population-based study of 501 individuals ages 75 to 86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%.[5] In the US, more than 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

Aortic stenosis does not cause substantial morbidity or mortality when the disease is mild or moderate in severity. By the time it becomes severe, there is an untreated mortality rate of approximately 50% within 2 years.[6] Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for up to 20 years.[6] However, these benefits are accompanied by a perioperative mortality of approximately 3% to 4% and substantial morbidity,[6] both of which increase with advancing age.

Unmet Needs

Many individuals with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of individuals presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities.[7] For individuals who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes.[8] Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction, and aortic regurgitation. Also, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in individuals who are at increased risk for open surgery.

Treatment

TAVI, also known as transcatheter aortic valve replacement (TAVR), has been developed in response to this unmet need and was originally intended as an alternative for individuals for

whom surgery was not an option due to prohibitive surgical risk or for individuals at high risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass.

Summary of Evidence

For individuals who have severe symptomatic aortic stenosis who are at prohibitive risk for open surgery who receive TAVI, the evidence includes a randomized controlled trial (RCT) comparing TAVI with medical management in individuals at prohibitive risk of surgery, a single-arm prospective trial, multiple case series, and multiple systematic reviews. The relevant outcomes are overall survival (OS), symptoms, morbid events, and treatment-related mortality and morbidity. For individuals who are not surgical candidates due to excessive surgical risk, the Placement of AoRTic TraNscathetER Valve Trial Edwards SAPIEN Transcatheter Heart Valve (PARTNER B) trial reported on results for individuals treated with TAVI by the transfemoral approach compared with continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI individuals at one year compared with medical care. This trial also reported improvements in other relevant clinical outcomes for the TAVI group. There was an increased risk of stroke and vascular complications in the TAVI group. Despite these concerns, the overall balance of benefits and risks from this trial indicate that health outcomes are improved. For individuals who are not surgical candidates, no randomized trials have compared the self-expandable valve with best medical therapy. However, results from the single-arm CoreValve Extreme Risk Pivotal Trial met trialists' pre-specified objective performance goal. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at high risk for open surgery who receive TAVI, the evidence includes two RCTs comparing TAVI with surgical repair in individuals at high risk for surgery and one RCT comparing two types of valves, multiple nonrandomized comparative studies, and systematic reviews of these studies. The relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. For individuals who are high risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at one year for the balloon-expandable valve compared with

open surgery. In this trial, TAVI individuals also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk individuals have reported no major differences in rates of mortality or stroke between the two procedures. Since the publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at one and two years for the self-expanding prosthesis. This trial reported no significant differences in stroke rates between groups. An RCT directly comparing the Portico valve with other FDA-approved valves found an increase in safety outcomes with Portico at 30 days but no major differences at two years. Gender-specific meta-analyses have found improved mortality with TAVI compared with surgical aortic valve replacement (SAVR) in women. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate risk for open surgery who receive TAVI, the evidence includes three RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, two RCTs only in individuals with intermediate risk, and multiple systematic reviews and nonrandomized cohort studies. The relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in individuals with intermediate risk for open surgery. Three of them, which included over 4,000 individuals combined, reported noninferiority of TAVI versus SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of individuals (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at two years for TAVI vs SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs 2%, p=0.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in individuals randomized to open surgery and permanent pacemaker requirement higher in individuals randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon et al (2010) RCT have suggested that the benefit of TAVI may be limited to individuals who are candidates for transfemoral access. Although several RCTs have two years of follow-up postprocedure, it is uncertain how many individuals require reoperation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at low risk for open surgery who receive TAVI, the evidence includes RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including individuals at low surgical risk and RCTS enrolling only low surgical risk individuals, systematic reviews, and nonrandomized cohort studies. The relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs (Evolut Low Risk Trial and the Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low-Risk

Individuals Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement [PARTNER 3]) have been conducted exclusively in individuals at low surgical risk and one RCT, Nordic Aortic Intervention Trial (NOTION), included predominantly individuals at low surgical risk. In the Evolut Low Risk Trial, transcatheter aortic valve replacement (TAVR) was noninferior to SAVR with respect to the composite outcome of death or disabling stroke at 24 months. In the PARTNER 3 trial, the rate of the composite of death, stroke, or rehospitalization at one year was significantly lower with TAVI than SAVR. In the NOTION trial, the risk of the composite outcome of death from any cause, stroke, or myocardial infarction (MI) at five years was similar for TAVI and SAVR and TAVR showed less structural valve deterioration than SAVR at six years. In the publicly sponsored UK TAVI trial, which was conducted in individuals aged 70 years or older with predominantly low surgical risk, TAVI was noninferior to SAVR with respect to all-cause mortality at one year. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have valve dysfunction and aortic stenosis or regurgitation after open surgical aortic valve repair who receive transcatheter aortic "valve-in-valve" (ViV) implantation, the evidence includes observational studies including registry data with follow-up ranging from one month to five years and systematic reviews. The relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Recent meta-analyses of observational studies have compared ViV TAVI to redo-SAVR and have reported a reduced risk of short-term mortality (<30 days) with ViV TAVI. Beyond 30 days, meta-analyses have reported mortality outcomes that were similarly favorable or improved with redo-SAVR. The PARTNER 2 registry reported a 50.6% rate of all-cause mortality after five years among individuals with high surgical risk; individuals who received a 23-mm SAPIEN XT valve had a significantly higher risk of mortality compared to those who received a 26-mm valve (hazard ratio, 1.55; 95% confidence interval, 1.09 to 2.20; p=.01). The CorHealth Ontario Cardiac Registry found that at 5 years after treatment, patients who underwent ViV TAVI had greater OS than rSAVR in a matched cohort of individuals (absolute risk difference, -7.5; 95% confidence interval, -12.6% to -2.3%). The Danish National Patient Registry found that ViV TAVI had similar mortality and rehospitalization outcomes compared to native valve TAVI at one- or five-years follow-up. Given that no RCTs are available, selection bias cannot be ruled out. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic aortic stenosis who receive a cerebral embolic protection (CEP) device while undergoing TAVI, the evidence includes one meta-analysis and four RCTs of individuals with low- to high-risk for open surgery. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. One meta-analysis found that patients with CEP had a lower rate of major adverse cardiac events, mortality, and stroke than patients with no CEP at 30 days post-TAVI; no differences were noted in the rate of vascular

complications, acute kidney injury, or major life-threatening bleeding. Three RCTs have primarily focused on the number and/or volume of new brain lesions detected on magnetic resonance imaging with unclear correlations to neurocognitive outcomes. Only one of these trials (CLEAN-TAVI) found a significant reduction in brain lesion number; however, the relevance of this trial is limited as it used a precursor to the currently marketed Sentinel device. The largest and most recent trial (PROTECTED TAVR) enrolled 3000 individuals and did not find a significant reduction in the incidence of periprocedural stroke within 72 hours or before hospital discharge. Prior trials have generally failed to demonstrate neurocognitive protection or significant reductions in major cardiac and cerebrovascular events. Studies have not stratified results by operative risk levels and have suggested differential benefits based on valve type. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02701283	Transcatheter Aortic Valve Replacement With the Medtronic Transcatheter Aortic Valve Replacement System In Patients at Low Risk for Surgical Aortic Valve Replacement	2223	Mar 2026
NCT05261204	Transcatheter Aortic Valve Implantation Versus Standard Surgical Aortic Valve Operation for Aortic-Valve Stenosis in Patients at Risk to Severe Valve Obstruction.	1950	Mar 2024
NCT05002088[a]	Retrospective Assessment of the Portico Transcatheter Aortic Valve for Valve-in-Valve Use	100	Jun 2027
NCT03042104[a]	Evaluation of Transcatheter Aortic Valve Replacement Compared to Surveillance for Patients with Asymptomatic Severe Aortic Stenosis	901	Mar 2032
NCT03112980	Randomized, Multi-Center, Event-Driven Trial of TAVI versus SAVR in Patients with Symptomatic Severe Aortic Valve Stenosis and Intermediate Risk of Mortality - DEDICATE	1417	Mar 2027

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01586910[a]	Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI)	1746 (actual enrollment)	Nov 2026
NCT01057173	Transcatheter Versus Surgical Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis (NOTION)	280	Apr 2033
NCT01314313[a]	The PARTNER II Trial "Placement of AoRTic TraNscathetER Valves Trial" (US) [Edwards Study 2010-12]	2032	Nov 2024
NCT02163850[a]	SALUS Trial: TranScatheter Aortic Valve Replacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Transcatheter Aortic Valve System	878	Dec 2021 (unknown)
NCT01737528	Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry)	16,000	Jun 2035
NCT02000115[a]	Portico Re-sheathable Transcatheter Aortic Valve System US IDE Trial	1150	Jul 2025
NCT02825134[a]	Nordic Aortic Valve Intervention Trial 2 - A Randomized Multicenter Comparison of Transcatheter Versus Surgical Aortic Valve Replacement in Younger Low Surgical Risk Patients With Severe Aortic Stenosis (NOTION-2)	372	Jun 2029
NCT02675114[a]	A Prospective, Randomized, Controlled, Multi-Center Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement (PARTNER 3)	1000	Dec 2029

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2024 Input

Clinical input was sought to help determine whether the use of transcatheter aortic valve-in-valve (ViV) implantation for individuals who have valve dysfunction and aortic stenosis or regurgitation after open surgical aortic valve repair provides a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 4 respondents, including: 3 physician-level responses with academic affiliations identified by specialty medical societies and 1 physician-level response identified by an academic health system.

For individuals with valve dysfunction and aortic stenosis or regurgitation after open surgical aortic valve repair, clinical input provides consistent support that the use of transcatheter ViV implantation provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.

The following patient selection criteria for transcatheter aortic valve replacement (TAVR) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (ViV) were informed by clinical input and the published evidence:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
- New York Heart Association heart failure class II, III, or IV symptoms; AND
- Individual is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); OR
- Individual is an operable candidate but is considered at increased surgical risk for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon; see Related Information section); OR
- Individual is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon).

Respondents noted that there are certain technical impediments that may increase the risk of redo surgical aortic valve replacement (rSAVR) that are not captured by STS risk score, including porcelain aorta, prior mediastinal surgeries, patent bypass grafts, or a particularly adherent left internal mammary artery. Additionally, elderly individuals that do not meet high-risk criteria can benefit from the early recovery offered by TAVR. Clinical input also emphasized that there is

unlikely to be equipoise for randomization of patients with structural bioprosthetic valve degeneration to aortic valve replacement via any modality versus conservative therapy.

2016 Input

In response to requests, input was received from two specialty societies (one of which provided two responses) and two academic medical centers (one of which provided three responses) while this policy was under review in 2016. Although there was no support for the use of valve-in-valve TAVI to replace a failed bioprosthetic valve in general use, there was general support for the use of valve-in-valve TAVI for patients at high and prohibitive risk for surgery.

2014 Input

In response to requests, input was received from two specialty societies (one of which provided two responses) and six academic medical centers while this policy was under review in 2014. All reviewers who responded considered TAVI medically necessary for patients with severe aortic stenosis with a calcified aortic annulus and New York Heart Association functional class II, III, or IV symptoms, and who are not candidates for open surgery or who are operable candidates but are at high risk for open surgery. Most reviewers would require a patient to have a left ventricular ejection fraction greater than 20% for the procedure to be medically necessary. All reviewers indicated support for limiting the use of TAVI to patients who are not candidates for open surgery or who are operable candidates but are at high-risk for open surgery, and most supported using the FDA definition of high risk and extreme risk for surgery. Most reviewers noted that self-expanding valves have been associated with higher rates of postprocedural pacemaker requirements but that neither type of valve was clearly superior to the other.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are

informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology and American Heart Association

In 2014, the American College of Cardiology and the American Heart Association published joint guidelines on the management of valvular heart disease.[117] Both groups issued a joint focused update in 2017.[118] In 2020, a new full guideline was published that replaces the 2014 revision and 2017 focused update.[119] The 2020 guidelines made the following recommendations on timing of intervention and choice of surgical or transcatheter intervention for treatment of aortic stenosis (see **Table 2**). Additionally, the guidelines state the following:

- "Treatment of severe aortic stenosis with either a transcatheter or surgical valve prosthesis should be based primarily on symptoms or reduced ventricular systolic function. Earlier intervention may be considered if indicated by results of exercise testing, biomarkers, rapid progression, or the presence of very severe stenosis."
- "Indications for TAVI are expanding as a result of multiple randomized trials of TAVI versus surgical aortic valve replacement. The choice of type of intervention for a patient with severe aortic stenosis should be a shared decision-making process that considers the lifetime risks and benefits associated with type of valve (mechanical versus bioprosthetic) and type of approach (transcatheter versus surgical)."

Table 2. Recommendations on Surgical or Transcatheter Intervention for Aortic Stenosis

Recommendation	COR	LOE
Timing of Intervention of AS		
"In adults with severe high-gradient AS (Stage D1) and symptoms of exertional dyspnea, heart failure, angina, syncope, or presyncope by history or on exercise testing, AVR is indicated."	I	A
"In asymptomatic patients with severe AS and a left ventricular ejection fraction <50% (Stage C2), AVR is indicated."	I	B
"In asymptomatic patients with severe AS (Stage C1) who are undergoing cardiac surgery for other indications, AVR is indicated."	I	B

"In symptomatic patients with low-flow, low-gradient severe AS with reduced left ventricular ejection fraction (Stage D2), AVR is recommended."	I	B
"In symptomatic patients with low-flow, low-gradient severe AS with reduced left ventricular ejection fraction (Stage D3), AVR is recommended if AS is the most likely cause of symptoms."	I	B
"In apparently asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable when an exercise test demonstrates decreased exercise tolerance (normalized for age and sex) or a fall in systolic blood pressure of ≥10 mmHg from baseline to peak exercise."	IIa	B
"In asymptomatic patients with very severe AS (defined as an aortic velocity of ≥5 m/s) and low surgical risk, AVR is reasonable."	IIa	B
"In apparently asymptomatic patients with severe AS (Stage C1) and low surgical risk, AVR is reasonable when the serum B-type natriuretic peptide level is >3 times normal."	IIa	B
"In asymptomatic patients with high-gradient severe AS (Stage C1) and low surgical risk, AVR is reasonable when serial testing shows an increase in aortic velocity ≥0.3 m/s per year."	IIa	B
"In asymptomatic patients with severe high-gradient AS (Stage C1) and a progressive decrease in left ventricular ejection fraction on at least 3 serial imaging studies to <60%, AVR may be considered.	IIb	B
"In patients with moderate AS (Stage B) who are undergoing cardiac surgery for other indications, AVR may be considered.	IIb	C
Choice of SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR is Appropriate		
"For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended."	I	A
"For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability."	I	A
"For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy of < 10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR."	I	A
"In asymptomatic patients with severe AS and a left ventricular ejection fraction <50% who are ≤80 years of age and have no anatomic contraindication to transfemoral TAVI, the decision between TAVI and SAVR should follow the same recommendations as for symptomatic patients in the 3 recommendations above."	I	B
"For asymptomatic patients with severe AS and an abnormal exercise test, very severe AS, rapid progression, or an elevated B-type natriuretic peptide, SAVR is recommended in preference to TAVI."	I	B
"For patients with an indication for AVR for whom a bioprosthetic valve is preferred but valve or vascular anatomy or other factors are not suitable for transfemoral TAVI, SAVR is recommended."	I	A

"For symptomatic patients of any age with severe AS and a high or prohibitive surgical risk, TAVI is recommended if predicted post-TAVI survival is >12 months with an acceptable quality of life."	I	A
"For symptomatic patients with severe AS for whom predicted post-TAVI or post-SAVR survival is <12 months or for whom minimal improvement in quality of life is expected, palliative care is recommended after shared decision-making, including discussion of patient preferences and values."	I	C
"In critically ill patients with severe AS, percutaneous aortic balloon dilation may be considered as a bridge to SAVR or TAVI."	IIb	C
Intervention for Prosthetic Valve Stenosis		
"In patients with symptomatic severe stenosis of a bioprosthetic or mechanical prosthetic valve, repeat surgical intervention is indicated unless surgical risk is prohibitive."	I	B
"For severely symptomatic patients with bioprosthetic aortic valve stenosis and high or prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a Comprehensive Valve Center."	IIa	B
"For patients with significant bioprosthetic valve stenosis attributable to suspected or documented valve thrombosis, oral anticoagulation with a VKA is reasonable."	IIa	B
Prosthetic Valve Regurgitation		
"In patients with intractable hemolysis or HF attributable to prosthetic transvalvular or paravalvular leak, surgery is recommended unless surgical risk is high or prohibitive."	I	B
"In asymptomatic patients with severe prosthetic regurgitation and low operative risk, surgery is reasonable."	IIa	B
"In patients with prosthetic paravalvular regurgitation with the following: 1) either intractable hemolysis or NYHA class III or IV symptoms and 2) who are at high or prohibitive surgical risk and 3) have anatomic features suitable for catheter-based therapy, percutaneous repair of paravalvular leak is reasonable when performed at a Comprehensive Valve Center."	IIa	B
"For patients with severe HF symptoms caused by bioprosthetic valve regurgitation who are at high to prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a Comprehensive Valve Center."	IIa	B

AS: aortic stenosis; AVR: aortic valve replacement; COR: class of recommendation; HR: heart failure; LOE: level of evidence; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation; ViV: valve-in-valve; VKA: vitamin K antagonist; NYHA: New York Heart Association..

National Institute for Health and Care Excellence

In June 2019, the National Institute For Health And Care Excellence (NICE) published interventional procedures guidance [IPG653] regarding ViV TAVI for aortic bioprosthetic valve dysfunction.[120] The guidance was informed by an Interventional procedure overview described

previously.[101] The guidance recommendation is that "Current evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) for aortic bioprosthetic dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit."

In November 2021, the NICE updated their guidance on heart valve disease. They recommend patients be offered TAVI if SAVR is contraindicated or the patient is at high surgical risk.[121]

Medicare National Coverage

The Centers for Medicare & Medicaid Services published a decision memo on the use of TAVR in 2012 and 2019.[122] The 2019 memo indicated that Centers for Medicare & Medicaid Services covers TAVI when used according to FDA indications when the following conditions are met:

- Device has FDA approval.
- The patient (preoperatively and postoperatively) is under the care of a heart team including an experienced cardiac surgeon and interventional cardiologist, who have independently examined the patient, as well as providers from other physician groups, advanced patient practitioners, nurses, research personnel and administrators
- The interventional cardiologist(s) and cardiac surgeon(s) jointly participate in the intra-operative technical aspects of TAVR
- The hospital meets qualifications for performing TAVR
- The heart team and hospital are participating in a prospective, national, audited registry that follows patients for at least one year and collects specific patient, practitioner and facility level outcomes
- The registry collects necessary data and has an analysis plan to address specific questions and results are reported publicly

The memo also stated that TAVR could be covered for non-FDA-approved indications under the Coverage with Evidence Development program. The following is a summary of the main conditions required for Coverage with Evidence Development:

- The interventional cardiologist(s) and cardiac surgeon(s) jointly participate in the intra-operative technical aspects of TAVR

TAVR is performed within a clinical study that has the following characteristics:

- "The clinical study must adhere to the… standards of scientific integrity and relevance to the Medicare population."
- The study must address quality of life and adverse events at follow-up periods of one year or longer.

The decision memo does not address concurrent use of a cerebral embolic protection device.

Regulatory Status

Multiple manufacturers have transcatheter aortic valve devices with US Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in **Table 3**.

Table 3. FDA-Approved Transcatheter Aortic Valve Device Systems

Device and Indication	Manufacturer	Date Cleared	PMA
Edwards SAPIEN Transcatheter Heart Valve System Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach)	Edwards Lifesciences	11/11	P100041
Edwards SAPIEN Transcatheter Heart Valve, Model 9000TFX Expanded to include high-risk aortic stenosis (transapical approach)	Edwards Lifesciences	10/12	P110021
Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories Severe native aortic valve stenosis at high or greater risk for open surgical therapy	Edwards Lifesciences	07/14	P130009
Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy	Edwards Lifesciences	10/15	P130009/ S034
Expanded to include severe aortic stenosis with intermediate surgical risk	Edwards Lifesciences	08/16	P130009/ S057
SAPIEN 3 THV System, a design iteration Severe aortic stenosis with high or greater risk for open surgical therapy	Edwards Lifesciences	6/15	P140031
Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy	Edwards Lifesciences	6/17	P140031/ S028

Device and Indication	Manufacturer	Date Cleared	PMA
SAPIEN 3 Ultra THV System, a design iteration Note: In August 2019, FDA issued a recall for the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System (Recall event ID: 83293) due to "reports of burst balloons which have resulted in significant difficulty retrieving the device into the sheath and withdrawing the system from the patient during procedures"	Edwards Lifesciences	12/18	P140031
Expanded to include severe aortic stenosis with low surgical risk	Edwards Lifesciences	08/19	P140031/ S085
Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy	Edwards Lifesciences	09/20	P140031/ S112
Medtronic CoreValve System Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy	Medtronic CoreValve	01/14	P130021
Expanded to include high risk for open surgical therapy	Medtronic CoreValve	06/16	P130021/ S002
Expanded to include intermediate risk for open surgical therapy	Medtronic CoreValve	07/17	P130021/ S033
Medtronic CoreValve Evolut R System Design iteration for valve and accessories	Medtronic CoreValve	06/15	P130021/ S014
Expanded to include intermediate risk for open surgical therapy	Medtronic CoreValve	07/17	P130021/ S033
Medtronic CoreValve Evolut PRO System Design iteration for valve and accessories, includes porcine pericardial tissue wrap	Medtronic CoreValve	03/17	P130021/ S029
Expanded to include intermediate risk for open surgical therapy	Medtronic CoreValve	07/17	P130021/ S033
Expanded to include severe aortic stenosis with low surgical risk	Medtronic CoreValve	08/19	P130021/ S058
Medtronic CoreValve Evolut PRO+ System (design iteration)	Medtronic CoreValve	08/19	P130021/ S059
Medtronic EvolutFX System (design iteration)	Medtronic CoreValve	8/21	P130021/ S091
LOTUS Edge Valve System Severe native aortic stenosis at high or greater risk for open surgical therapy	Boston Scientific Corporation	04/19	P180029

Device and Indication	Manufacturer	Date Cleared	PMA
(See Note below)			
Portico with FlexNav Severe native aortic stenosis at high or greater risk for open surgical therapy	Abbott Medical	09/21	P190023
Navitor Transcatheter Aortic Valve Implantation System with FlexNav Severe native aortic stenosis at high or greater risk for open surgical therapy	Abbott Medical	10/23	P190023/ S016

FDA: US Food and Drug Administration: PMA: premarket approval.

Note: In January 2021, Boston Scientific Corporation announced a global, voluntary recall of all unused inventory of the LOTUS Edge Valve System due to complexities associated with the product delivery system.[9] There are no safety concerns for patents who have the LOTUS Edge Valve System currently implanted. Boston Scientific has chosen to retire the entire LOTUS product platform immediately rather than develop and reintroduce an enhanced delivery system. All related commercial, clinical, research and development, and manufacturing activities will cease.

Other transcatheter aortic valve systems are under development:

- JenaValve (JenaValve Technology); repositionable valve designed for transapical placement. The FDA granted breakthrough designation to this device system in January 2020.
- Acurate aortic valve platform (Boston Scientific); designed for individuals with severe aortic stenosis indicated for transcatheter aortic valve replacement who are at low, intermediate, or high risk of operative mortality. The system received Conformité Européene (CE) mark approval in Europe as of 2020 but is not approved for non-investigational use in the US. The pivotal Acurate IDE trial will be completed in 2024 (NCT03735667)

In June 2017, the Sentinel Cerebral Protection System (Boston Scientific, previously Claret Medical, Inc.) was granted a de novo classification by the FDA (DEN160043; class II; product code: PUM.)[10] The Sentinel system is a temporary catheter indicated for use as an embolic protection deice to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 mm to 15 mm for the brachiocephalic and 6.5 mm to 10 mm in the left common carotid. The new classification applies to this device and substantially equivalent devices of this generic type.

On August 3, 2021, the FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee met to discuss and make recommendations on the 510(k) submission for the TriGUARD 3 Cerebral Embolic Protection Device (Keystone Heart).[11] With the Sentinel system serving as the predicate device, the panel expressed that the proposed indications for use of the TriGUARD 3 device were not supported by the safety and effectiveness data from the REFLECT II trial. Previously, the TriGUARD 3 device was granted Conformité Européene (CE) mark approval in Europe in March 2020. [12,11]

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History

Date	Comments
02/27/12	New Policy – Add to Surgery section. Policy created with literature search through October 2011; considered medically necessary for patients who are not surgical candidates; investigational for all other indications.
09/27/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
02/11/13	Replace policy. Policy updated with literature review, references 7, 15, 16, 18, 20, 23-28, 30 added. Medically necessary indications added for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach. Investigational statement added for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in-Valve approach), and for vascular approaches other than transfemoral or transapical. Codes updated.
12/23/13	Coding Update. Add new CPT 33366, effective 01/01/14; 0318T discontinued effective 12/31/13; deleted codes 0256T – 0259T removed.
02/10/14	Replace policy. Policy updated with literature review through November 15, 2013. References 8, 18, 19, 22, 23, 27 added. Policy statement revised to include medically necessary indication for TAVI by the transapical approach for patients who are not suitable candidates for open surgery. ICD-10 Procedure codes 35.05 and 35.22 removed from the policy; they were provided for informational purposes only.
12/17/14	Annual Review. Policy statement revised to remove statement that "procedures performed via the transaxillary, transiliac, transaortic, or other approaches" are investigational, to reflect the approval of the CoreValve device that is labeled for use via transaxillary, transfemoral, and transaortic approaches. Policy statement added stating that devices should be used according to their FDA approved indication. Clinical input supported proposed policy statements. Policy updated with literature review through September 1, 2014, and the results of clinical input. References 9-10, 15-17, 23, 28-34, 36, 41-43, 45, 47, 49-52, 57-59 added; others renumbered/removed. Policy statements changed as noted. ICD-9 and ICD-10 diagnosis and procedure codes removed; these do not relate to policy adjudication.
12/08/15	Annual Review. Policy reviewed. No new references added. Policy statements unchanged.
02/01/16	Coding update. Added 93799.

Date	Comments
11/01/16	Annual Review, changes approved October 11, 2016. Medically necessary policy statement added for valve-in-valve implantation in patients at high or prohibitive risk for open surgery. Policy updated with literature review through December 9, 2015, references added. Policy statement added as noted. Coding update, removed unlisted CPT code 93799.
05/01/17	Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 22, 2016; references 20, 31-34, 45, 48-55, and 85 added. Policy statements unchanged.
10/24/17	Policy moved to new format; no change to policy statements.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 19, 26, 37, 42-50, 58-60, 68, and 82-83 added. Policy statements changed to add patients at intermediate surgical risk to first medically necessary statement.
04/01/19	Minor update, added Documentation Requirements section.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through February 2019; references 73-76 added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020. Policy updated with literature review through November 2019; references added. Medically Necessary policy statement related to patients with native valve aortic stenosis changed to add an exclusion for patients with unicuspid or bicuspid aortic valve and to add an inclusion for patients at low risk for open surgery, Policy statement changes are effective April 1, 2020.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy statements unchanged.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through January 9, 2021; references added. Policy statements unchanged.
01/01/22	New policy approved December 14, 2021. This policy replaces 7.01.132 Transcatheter Aortic-Valve Implantation for Aortic Stenosis. This is effectively a policy renumber. Added policy statement that use of a cerebral embolic protection device during TAVR procedures is considered investigational. CPT code 33370 added. HCPCS code C1884 added.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through December 29, 2021; references added. Policy statements unchanged.
05/01/23	Policy renumbered to 7.01.132 Transcatheter Aortic-Valve Implantation for Aortic Stenosis from 7.01.585, approved April 11, 2023. Policy updated with literature review through January 3, 2023; references added. Minor editorial refinements to existing policy statements; intent unchanged. Changed the wording from "patient" to

Date	Comments
	"individual" throughout the policy for standardization. Removed effective date from CPT code 33370.
05/01/24	Annual Review, approved April 9, 2024. Policy updated with literature review through January 8, 2024; references added. Policy statements refined based on review of clinical input. For TAVI and ViV TAVI, the criterion of left ventricular ejection fraction greater than 20% was removed. A statement was added for consideration of individuals who may be at high risk of open surgery but not demonstrated on Society of Thoracic Surgeons risk score, 'Individual is considered at increased surgical risk for an open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon)'.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.