BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.132 Transcatheter Aortic-Valve Implantation for Aortic Stenosis

Effective Policy Date: July 1, 2022

Original Policy Date: December 2012

Related Policies:

None

Transcatheter Aortic-Valve Implantation for Aortic Stenosis

Description

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Aortic stenosis is narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Patients 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) is being evaluated as an alternative to open surgery for patients with aortic stenosis and to nonsurgical therapy for patients with a prohibitive risk for surgery.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of transcatheter aortic valve replacement improves the net health outcome in patients with severe aortic stenosis, depending on an individual's risk for open-heart surgery.

POLICY STATEMENT

Transcatheter aortic valve replacement with an U.S. Food and Drug Administration (FDA) approved transcatheter heart valve system, performed via an approach consistent with the device's FDA approved labeling, may be considered **medically necessary** for patients with native valve aortic stenosis when all of the following conditions are present:

- Severe aortic stenosis (see Policy Guidelines section) with a calcified aortic annulus; AND
- New York Heart Association heart failure class II, III, or IV symptoms; AND
- Left ventricular ejection fraction greater than 20%; AND
- Patient 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; AND
- Left ventricular ejection fraction greater than 20%; AND
- Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery (see Policy Guidelines section).

Transcatheter aortic valve replacement is considered **not medically necessary** for all other indications.

POLICY GUIDELINES

The U.S. 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.

The 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.

The FDA definition of intermediate risk is:

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

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

For the use of the SAPIEN or CoreValve devices, severe aortic stenosis is defined by the presence of 1 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 mmHg
- A peak aortic-jet velocity greater than or equal to 4.0 m/s.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Multiple manufacturers have transcatheter aortic valve devices with U.S. Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in Table 1.

Table 1. 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)		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		07/14	P130009
• Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy		10/15	P130009/S034
• Expanded to include severe aortic stenosis with intermediate surgical risk		08/16	P130009/S057
• 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".		12/18	P140031
• Expanded to include severe aortic stenosis with low surgical risk		08/19	P140031/S085
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		06/16	P130021/S002
• Expanded to include intermediate risk for open surgical therapy		07/17	P130021/S033
• Medtronic CoreValve Evolut R System™ (design iteration for valve and accessories)		06/15	P130021/S014
• Expanded to include intermediate risk for open surgical therapy		07/17	P130021/S033
• Medtronic CoreValve Evolut PRO System™ (design iteration for valve and accessories, includes porcine pericardial tissue wrap)		03/17	P130021/S029
• Expanded to include intermediate risk for open surgical therapy		07/17	P130021/S033
• Expanded to include severe aortic stenosis with low surgical risk		08/19	P130021/S058
• Medtronic CoreValve Evolut PRO+ System™ (design iteration)		08/19	P130021/S059
• Medtronic Evolut™ FX System (design iteration)		08/21	P130021/S091
LOTUS Edge™ Valve System • Severe native aortic stenosis at high or greater risk for open surgical therapy • **See Note**	Boston Scientific Corporation	04/19	P180029
Portico™ with FlexNav™ • Severe native aortic stenosis at high or greater risk for open surgical therapy	Abbott Medical	09/21	P190023

FDA: U.S. 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. The following repositionable valve is under investigation:

- JenaValve™ (JenaValve Technology); designed for transapical placement. The FDA granted breakthrough designation to this device system in January 2020.

RATIONALE

Summary of Evidence

For individuals who have severe symptomatic aortic stenosis who are at prohibitive risk for open surgery who receive transcatheter aortic valve implantation (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. Relevant outcomes are overall survival (OS), symptoms, morbid events, and treatment-related mortality and morbidity. For patients 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 patients 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 patients at 1 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 patients 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" prespecified 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 2 RCTs comparing TAVI with surgical repair in individuals at high-risk for surgery and 1 RCT comparing 2 types of valves, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are high-risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the 2 procedures. Since the publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 and 2 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 2 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 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate-risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in patients with intermediate-risk for open surgery. Three of them, which included over 4000 patients combined, reported noninferiority of TAVI versus SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of patients (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 2 years for TAVI versus SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs. 2%, p=.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in patients randomized to open surgery and permanent pacemaker requirement higher in patients 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 patients who are candidates for transfemoral access. Although several RCTs have 2 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 patients at low surgical risk and RCTs enrolling only low surgical risk patients, systematic reviews, and nonrandomized cohort studies. 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 Patients Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement [PARTNER 3]) have been conducted exclusively in patients at low surgical risk and 1 RCT, Nordic Aortic Intervention Trial included predominantly patients at low surgical risk. In the Evolut Low Risk Trial, transcatheter aortic valve replacement 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 1 year was significantly lower with TAVI than SAVR. In the Nordic Aortic Intervention Trial, the risk of the composite outcome of death from any cause, stroke, or myocardial infarction at 5 years was similar for TAVI and SAVR and transcatheter aortic valve replacement showed less structural valve deterioration than SAVR at 6 years. 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" implantation, the evidence includes observational studies including registry data with follow-up ranging from 1 month to 3 years and systematic reviews. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Systematic reviews of observational studies have compared valve-in-valve TAVI to redo SAVR and have reported similar mortality, stroke, and survival rates for the 2 procedures. However, selection bias cannot be ruled out given that no RCTs are available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" 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.[90,] Both groups issued a joint focused update in 2017[91,] In 2020, a new full guideline was published that replaces the 2014 revision and 2017 focused update.[92,] The 2020 guidelines made the following recommendations on timing of intervention and choice of surgical or transcatheter intervention for treatment of aortic stenosis (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

AS: aortic stenosis; AVR: aortic valve replacement; COR: class of recommendation; LOE: level of evidence; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

National Institute for Health and Care Excellence

In June 2019, the NICE published interventional procedures guidance [IPG653] regarding valve-in-valve TAVI for aortic bioprosthetic valve dysfunction.[93,] The guidance was informed by an Interventional procedure overview described previously.[86,] 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.[94,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services published a decision memo on the use of TAVR in 2012 and 2019.[95,] The 2019 memo indicated that the 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 1 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 1 year or longer.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
March 2013	Replace policy	Policy updated with literature review, references 7, 15, 16, 18, 20, 22-27, 29 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. Not medically necessary statement added for treatment of degenerated bioprosthetic valve or failed TAVI (Valve-in- Valve approach), and for vascular approaches other than transfemoral or transapical.
March 2014	Replace policy	Policy updated with literature review, adding references 8, 18, 19, 22, 23, 27. Policy statement revised to include medically necessary indication for TAVI by the transapical approach for patients who are not suitable candidates for open surgery.
December 2014	Replace policy	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, and 57-59 added. 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. A statement was added to the policy statement that devices should be used according to their FDA approved indication
September 2016	Replace policy	Policy updated with literature review, references 8-10, 15, 21, 25- 27, 30, 36, 41-45, 48, 54-56, 58, 74-75, and 78 added. Medically necessary policy statement added for valve-in- valve implantation in patients at high or prohibitive risk for open surgery. Policy statements revised to include intermediate risk of surgical mortality based on expansion of FDA approvals of Sapien 3 and Sapien XT valves.
June 2018	Replace policy	Policy updated with literature review through February 2, 2018; references 19-20, 26, 31-34, 37, 42-55, 58-60, 68, 82-83 and 85 added.
June 2019	Replace policy	Policy updated with literature review through February 1, 2019; references 73-76 added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through November 19, 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.
June 2021	Replace policy	Policy updated with literature review through January 9, 2021; references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through December 29, 2021; references added. Policy statements unchanged.