



# Louisiana

## Transcatheter Aortic Valve Implantation for Aortic Stenosis

**Policy #** 00406

**Original Effective Date:** 03/19/2014

**Current Effective Date:** 06/14/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Transcatheter Pulmonary Valve Implantation is addressed separately in medical policy 00576.*

### When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transcatheter aortic valve replacement (TAVR) with an FDA-approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling, for patients with native valve aortic stenosis **eligible for coverage.\*\***

#### Patient Selection Criteria

Coverage eligibility will be met for transcatheter aortic valve replacement (TAVR), with an FDA-approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling for patients with native valve aortic stenosis when all of the following conditions are present:

- Severe aortic stenosis with a calcified aortic annulus; AND
- New York Heart Association (NYHA) 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

Based on review of available data, the Company may consider transcatheter aortic valve replacement (TAVR) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) to be **eligible for coverage.\*\***

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### Patient Selection Criteria

Coverage eligibility will be met for transcatheter aortic valve replacement (TAVR) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) when all of the following are present:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
- NYHA 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.

*Note: 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.

*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 device, 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  $1 \text{ cm}^2$
- An aortic valve area index of less than or equal to  $0.6 \text{ cm}^2/\text{m}^2$
- 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

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## **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers transcatheter aortic valve replacement (TAVR) for all other indications to be **investigational**.\*

The use of transcatheter aortic valve replacement (TAVR) when patient selection criteria are not met is considered to be **investigational**.\*

## **Background/Overview**

### **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. 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. Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis, ie, 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 patients 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, increasing up to 8% of people by age 85 years. In the Helsinki Aging Study (1993), a population-based study of 501 patients, ages 75 to 86 years, the

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prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%. In the United States, more than 50000 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. Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for up to 20 years. However, these benefits are accompanied by perioperative mortality of approximately 3% to 4% and substantial morbidity, both of which increase with advancing age.

### **Unmet Needs**

Many patients with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of patients 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. For patients 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. 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 patients at increased risk for open surgery.

### **Treatment**

Transcatheter aortic valve implantation, also known as transcatheter aortic valve replacement, has been developed in response to this unmet need and was originally intended as an alternative for patients for whom surgery was not an option due to prohibitive surgical risk or for patients 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

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secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Multiple manufacturers have transcatheter aortic valve devices with U.S. FDA approval. Regulatory status data for these devices are listed in Table 1.

**Table 1. FDA Approved Transcatheter Aortic Valve Device Systems**

<b>Device and Indication</b>	<b>Manufacturer</b>	<b>Date Cleared</b>	<b>PMA</b>
Edwards SAPIEN Transcatheter Heart Valve System™‡ <ul style="list-style-type: none"> <li>Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach)</li> </ul>	Edwards Lifesciences	11/11	P100041
<ul style="list-style-type: none"> <li>Edwards SAPIEN™‡ Transcatheter Heart Valve, Model 9000TFX</li> <li>Expanded to include high-risk aortic stenosis (transapical approach)</li> </ul>		10/12	P110021
<ul style="list-style-type: none"> <li>Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories</li> <li>Severe native aortic valve stenosis at high or greater risk for open surgical therapy</li> </ul>		07/14	P130009
<ul style="list-style-type: none"> <li>Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy</li> </ul>		10/15	P130009/S034

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<ul style="list-style-type: none"> <li>Expanded to include severe aortic stenosis with intermediate surgical risk</li> </ul>	•	08/16	P130009/S057
<ul style="list-style-type: none"> <li>SAPIEN 3 Ultra THV System, a design iteration</li> </ul> <p>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".</p>		12/18	P140031
<ul style="list-style-type: none"> <li>Expanded to include severe aortic stenosis with low surgical risk</li> </ul>	•	08/19	P140031/S085
<p>Medtronic CoreValve System™‡</p> <ul style="list-style-type: none"> <li>Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy</li> </ul>	Medtronic CoreValve	01/14	P130021
<ul style="list-style-type: none"> <li>Expanded to include high-risk for open surgical therapy</li> </ul>		06/16	P130021/S002
<ul style="list-style-type: none"> <li>Expanded to include intermediate risk for open surgical therapy</li> </ul>		07/17	P130021/S033
<ul style="list-style-type: none"> <li>Medtronic CoreValve Evolut R System™‡ (design iteration for valve and accessories)</li> </ul>	•	06/15	P130021/S014
<ul style="list-style-type: none"> <li>Expanded to include intermediate risk for open surgical therapy</li> </ul>		07/17	P130021/S033

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<ul style="list-style-type: none"> <li>Medtronic CoreValve Evolut PRO System™‡ (design iteration for valve and accessories, includes porcine pericardial tissue wrap)</li> </ul>	•	03/17	P130021/S029
<ul style="list-style-type: none"> <li>Expanded to include intermediate risk for open surgical therapy</li> </ul>		07/17	P130021/S033
<ul style="list-style-type: none"> <li>Expanded to include severe aortic stenosis with low surgical risk</li> </ul>	•	08/19	P130021/S058
<ul style="list-style-type: none"> <li>Medtronic CoreValve Evolut PRO+ System™‡ (design iteration)</li> </ul>	•	08/19	P130021/S059
<p>LOTUS Edge™‡ Valve System</p> <ul style="list-style-type: none"> <li>Severe native aortic stenosis at high or greater risk for open surgical therapy</li> <li><b>See Note</b></li> </ul>	Boston Scientific Corporation	04/19	P180029

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. There are no safety concerns for patients 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 valves are under investigation:

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

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### **Rationale/Source**

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 (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.

### **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 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

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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. In an RCT directly comparing the self-expandable with the balloon-expandable valve among surgically high-risk patients, the devices had similar 30-day mortality outcomes, although the self-expandable valve was associated with higher rates of residual aortic regurgitation and need for a new permanent pacemaker. Evidence from RCT and nonrandomized studies has suggested that TAVI with a self-expanding device is associated with higher rates for permanent pacemakers post procedure. However, survival rates appear to be similar between device types, and the evidence does not support the superiority of 1 device over another in all patients. Two sex-specific studies were also identified in a literature search with the objective of observing mortality rates in women undergoing TAVI or surgical aortic valve replacement (SAVR). Results were varied, and further study is needed. 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=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 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 post

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procedure, 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 a 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.

### **Additional Information**

#### **2016 Input**

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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**

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 U.S. 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.

### **Supplemental Information**

The purpose of the Supplemental Information is to provide reference material regarding clinical input, existing practice guidelines and position statements, U.S. Preventive Services Task Force Recommendations and Medicare National Coverage Decisions and registered, ongoing clinical trials. Inclusion in the Supplemental Information does not imply endorsement or that the information is used in the evidence review.

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

### **Clinical Input 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,

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input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### **2016 Input**

In response to requests, input was received from 2 specialty societies (1 of which provided 2 responses) and 2 academic medical centers (1 of which provided 3 responses) while this policy was under review in 2016. Although there was no support for the use of valve-in-valve transcatheter aortic valve implantation (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 2 specialty societies (1 of which provided 2 responses) and 6 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 U.S. 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**

### **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. Both groups issued a joint focused update in 2017. In 2020, a new full guideline was published that replaces the 2014 revision and 2017 focused update. 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:

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- "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
<i>Timing of Intervention of AS</i>		
"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 $\geq 10$ mmHg from baseline to peak exercise."	IIa	B

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"In asymptomatic patients with very severe AS (defined as an aortic velocity of $\geq 5$ 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 $\geq 0.3$ 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
<b><i>Choice of SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR is Appropriate</i></b>		
"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 $\leq 80$ 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

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"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; TAVR: transcatheter aortic valve replacement.

### National Institute for Health and Care Excellence

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

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

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The Centers for Medicare & Medicaid Services published a decision memo on the use of TAVR in 2012 and 2019. 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 experienced a 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

TAVI 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.

### **Ongoing and Unpublished Clinical Trials**

Some currently ongoing trials that might influence this review are listed in Table 3.

### **Table 3. Summary of Key Trials**

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NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03042104	Evaluation of Transcatheter Aortic Valve Replacement Compared to Surveillance for Patients with Asymptomatic Severe Aortic Stenosis	1109	Dec 2031
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	1760	Dec 2026
NCT01586910 <sup>a</sup>	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 2023
NCT02661451 <sup>a</sup>	Transcatheter Aortic Valve Replacement to UNload the Left Ventricle in Patients With ADvanced Heart Failure: A Randomized Trial (TAVR UNLOAD)	300	Mar 2022
NCT02436655	Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis: (AVATAR Trial): A Multicentre Randomized Controlled Trial	312	Jun 2021
NCT01314313 <sup>a</sup>	The PARTNER II Trial "Placement of AoRTic TraNscathetER Valves Trial" (US)	2032	Nov 2024
NCT02163850 <sup>a</sup>	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

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01737528	Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry)	16,000	Jun 2022
NCT02249000	Safety and Clinical Performance of the Self-expanding Transcatheter BIOVALVE Prosthesis in Subjects With Severe Symptomatic Aortic Stenosis Suitable for Transfemoral Transcatheter Aortic Valve Implantation	86	Dec 2022
NCT02628899	Feasibility of Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic, Severe Aortic Stenosis	300	Jan 2023
NCT02000115	Portico Re-sheathable Transcatheter Aortic Valve System US IDE Trial	1268	Jul 2025
NCT02825134	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)	992	Jun 2029

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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### **Policy History**

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- 03/06/2014 Medical Policy Committee review
- 03/19/2014 Medical Policy Implementation Committee approval. New policy.
- 03/05/2015 Medical Policy Committee review
- 03/20/2015 Medical Policy Implementation Committee approval. Added “FDA approved” to the eligible for coverage statement. Updated rationale/source and references.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 03/05/2015 Medical Policy Committee review
- 03/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 05/05/2016 Medical Policy Committee review
- 05/18/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 11/03/2016 Medical Policy Committee review
- 11/16/2016 Medical Policy Implementation Committee approval. Added coverage statement for valve in valve for patient at high or prohibitive risk for open surgery.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 05/04/2017 Medical Policy Committee review
- 05/17/2017 Medical Policy Implementation Committee approval. Added “native valve” to coverage statement.
- 06/07/2018 Medical Policy Committee review
- 06/20/2018 Medical Policy Implementation Committee approval. Policy statements changed to add patients at intermediate surgical risk to first eligible for coverage statement.

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08/14/2018 Coding update  
06/06/2019 Medical Policy Committee review  
06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
03/05/2020 Medical Policy Committee review  
03/11/2020 Medical Policy Implementation Committee approval. Eligible for coverage 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.  
Removed “Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high or intermediate risk for open surgery.” From criteria section.  
7/20/2020 Updated coverage criteria statement  
05/06/2021 Medical Policy Committee review  
05/12/2021 Medical Policy Implementation Committee approval. FDA updated. No change to coverage.  
Next Scheduled Review Date: 05/2022

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, 33369
HCPCS	No codes
ICD-10 Diagnosis	I06.0-I06.9, I08.0, I08.8-I08.9, I35.0-I35.9

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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