# Transcatheter Aortic Valve Implantation for Aortic Stenosis

**Policy #** 00406
Original Effective Date: 03/19/2014
Current Effective Date: 05/13/2024

*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 U.S. FDA-approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling, for individuals with native valve aortic stenosis **eligible for coverage.****

Patient Selection Criteria

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

- Severe aortic stenosis (see Policy Guidelines section) with a calcified aortic valve; AND
- New York Heart Association (NYHA) heart failure Class II, III or IV symptoms; AND
- Individual 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
- One of the following:
  - 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
  - Individual is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon; see Policy Guidelines section).

# 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.***

Based on review of available data, the Company considers the use of transcatheter aortic valve replacement (TAVR) when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers the use of a cerebral embolic protection device (e.g., Sentinel) during transcatheter aortic valve replacement procedures to be **investigational.***

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# Policy Guidelines

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

The U.S. 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%.

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.

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# 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 aged 75 to 86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%. In the United States, 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. 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 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. Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in Table 1.

**Table 1. U.S. Food and Drug Administration Approved Transcatheter Aortic Valve Device Systems**

| Device and Indication | Manufacturer | Date Cleared | PMA |
|---|---|---|---|
| Edwards SAPIEN Transcatheter Heart Valve System™‡<br>• 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<br>• Expanded to include high-risk aortic stenosis (transapical approach) | | 10/12 | P110021 |
| • Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories<br>• Severe native aortic valve stenosis at high or greater risk for open surgical therapy | | 07/14 | P130009 |
| • Expanded to include failure of a bioprosthetic valve with 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 THV System, a design iteration<br>• Severe aortic stenosis with high or greater risk for open surgical therapy | • | 06/15 | P140031 |

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| • Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy | • | 06/17 | P140031/S028 |
| • SAPIEN 3 Ultra THV System, a design iteration<br><br>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 |
| • Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy | • | 09/20 | P140031/S112 |
| Medtronic CoreValve System™‡<br><br>• 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 |

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| • 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<br>• Severe native aortic stenosis at high or greater risk for open surgical therapy<br>• **See Note** | Boston Scientific Corporation | 04/19 | P180029 |
| Portico™‡ with FlexNav™‡ | Abbott Medical | 09/21 | P190023 |

| | | | |
|---|---|---|---|
| • Severe native aortic stenosis at high or greater risk for open surgical therapy | | | |
| Navitor™‡ Transcatheter Aortic Valve Implantation System with FlexNav™‡<br><br>• Severe native aortic stenosis at high or greater risk for open surgical therapy | Abbott Medical | 10/23 | P190023/S016 |

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:

- 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). The Sentinel system is a temporary catheter indicated for use as an embolic protection device 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). 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 CE mark approval in Europe in March 2020.

# Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 (TAVR), 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 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 United States Food and Drug Administration (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 post 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. In the publicly sponsored UK TAVI trial, which was conducted in patients aged 70 years or older with predominantly low surgical risk, TAVI was noninferior to SAVR with respect to all-cause mortality at 1 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 1 month to 5 years and systematic reviews. 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-surgical aortic valve replacement (rSAVR) 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 rSAVR. The PARTNER 2 registry reported a 50.6% rate of all-cause mortality after 5 years among patients with high surgical risk; patients 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 patients (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 1 or 5 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 1 meta-analysis and 4 RCTs of patients 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 1 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 patients 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.

# Supplemental Information

**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, 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 Policy Guidelines section); OR
- Individual is considered at increased surgical risk for open surgery (eg, 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 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 ViV transcatheter aortic valve implantation (TAVI) to replace a failed bioprosthetic valve in general use, there was general support for the use of ViV 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. Food and Drug Administration (FDA) definition of high-risk and extreme risk for surgery. Most

reviewers noted that self-expanding valves have been associated with higher rates of post procedural pacemaker requirements but that neither type of valve was clearly superior to the other.

**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. 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:

- "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, HF, 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 |

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| "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- | IIa | B |

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|---|---|---|
| based therapy, percutaneous repair of paravalvular leak is reasonable when performed at a Comprehensive Valve Center." | | |
| "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 NICE published interventional procedures guidance [IPG653] regarding ViV 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."

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

**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. 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.

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

**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**

| 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 |
| 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) | 2032 | Nov 2024 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| 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 (PORTICO-IDE) | 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.

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# Policy History

Original Effective Date: 03/19/2014
Current Effective Date: 05/13/2024

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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. |

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| 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. |
| 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.<br>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. |
| 07/20/2022 | Coding update |
| 05/06/2021 | Medical Policy Committee review |
| 05/12/2021 | Medical Policy Implementation Committee approval. FDA updated. No change to coverage. |
| 05/05/2022 | Medical Policy Committee review |
| 05/11/2022 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 04/06/2023 | Medical Policy Committee review |

Policy # 00406
Original Effective Date: 03/19/2014
Current Effective Date: 05/13/2024

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| 04/12/2023 | Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company considers the use of a cerebral embolic protection device (e.g., Sentinel) during transcatheter aortic valve replacement procedures to be investigational." |
| 07/24/2023 | Coding update |
| 04/04/2024 | Medical Policy Committee review |
| 04/10/2024 | Medical Policy Implementation Committee approval. 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 OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon). Added Policy Guideline section. |

Next Scheduled Review Date: 04/2025

# 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 2023 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.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which*

*contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

CPT is a registered trademark of the American Medical Association.

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, 33370 |
| HCPCS | C1889 |
| ICD-10 Diagnosis | I06.0, I06.2, I08.0, I08.2, I08.3, I08.8, I08.9, I35.0<br>All related diagnoses |

*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 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.

**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.