



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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 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
- 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.****

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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
- Individual is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or individual is an operable candidate but is at high risk for open surgery.

Note: 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.

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 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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**.*

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 bioprosthesis or mechanical valve.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

Disease Burden

Aortic stenosis is a relatively common disorder in elderly individuals and is the most common acquired valve disorder in the United States. Approximately 2% to 4% of people older than 65 years of age have evidence of significant aortic stenosis, increasing up to 8% of people by age 85 years. In the Helsinki Aging Study (1993), a population-based study of 501 individuals 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 individuals with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of individuals presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities. For individuals who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes. Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction, and aortic regurgitation. Also, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in individuals 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 individuals for whom surgery was not an option due to prohibitive surgical risk or for individuals at high-risk for open surgery. The procedure is performed percutaneously, most often through the

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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. FDA approval. Regulatory status data for these devices are listed in Table 1.

Table 1. FDA Approved Transcatheter Aortic Valve Device Systems

Device and Indication	Manufacturer	Date Cleared	PMA
Edwards SAPIEN Transcatheter Heart Valve System ^{TM†} <ul style="list-style-type: none"> Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach) 	Edwards Lifesciences	11/11	P100041
<ul style="list-style-type: none"> Edwards SAPIEN^{TM†} Transcatheter Heart Valve, Model 9000TFX Expanded to include high-risk aortic stenosis (transapical approach) 		10/12	P110021
<ul style="list-style-type: none"> Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories 		07/14	P130009

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

<ul style="list-style-type: none"> Severe native aortic valve stenosis at high or greater risk for open surgical therapy 			
<ul style="list-style-type: none"> Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy 		10/15	P130009/S034
<ul style="list-style-type: none"> Expanded to include severe aortic stenosis with intermediate surgical risk 	•	08/16	P130009/S057
<ul style="list-style-type: none"> SAPIEN 3 THV System, a design iteration Severe aortic stenosis with high or greater risk for open surgical therapy 	•	06/15	P140031
<ul style="list-style-type: none"> Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy 	•	06/17	P140031/S028
<ul style="list-style-type: none"> SAPIEN 3 Ultra THV System, a design iteration <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"> Expanded to include severe aortic stenosis with low surgical risk 	•	08/19	P140031/S085
<ul style="list-style-type: none"> Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy 	•	09/20	P140031/S112

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

Medtronic CoreValve System ^{TM‡} <ul style="list-style-type: none"> Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy 	Medtronic CoreValve	01/14	P130021
<ul style="list-style-type: none"> Expanded to include high-risk for open surgical therapy 		06/16	P130021/S002
<ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy 		07/17	P130021/S033
<ul style="list-style-type: none"> Medtronic CoreValve Evolut R System^{TM‡} (design iteration for valve and accessories) 	•	06/15	P130021/S014
<ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy 		07/17	P130021/S033
<ul style="list-style-type: none"> Medtronic CoreValve Evolut PRO System^{TM‡} (design iteration for valve and accessories, includes porcine pericardial tissue wrap) 	•	03/17	P130021/S029
<ul style="list-style-type: none"> Expanded to include intermediate risk for open surgical therapy 		07/17	P130021/S033
<ul style="list-style-type: none"> Expanded to include severe aortic stenosis with low surgical risk 	•	08/19	P130021/S058
<ul style="list-style-type: none"> Medtronic CoreValve Evolut PRO+ System^{TM‡} (design iteration) 	•	08/19	P130021/S059

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

<ul style="list-style-type: none"> Medtronic EvolutTM FX System (design iteration) 	<ul style="list-style-type: none"> 	08/21	P130021/S091
LOTUS Edge TM Valve System <ul style="list-style-type: none"> Severe native aortic stenosis at high or greater risk for open surgical therapy See Note 	Boston Scientific Corporation	04/19	P180029
Portico TM with FlexNav TM <ul style="list-style-type: none"> Severe native aortic stenosis at high or greater risk for open surgical therapy 	Abbott Medical	09/21	P190023

FDA: U.S. Food and Drug Administration: PMA: premarket approval.

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

Other transcatheter aortic valve systems are under development. The following repositionable valve is under investigation:

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

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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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 3TM 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 Conformité Européenne (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. Individuals with untreated, symptomatic severe aortic stenosis have a poor prognosis. Valve replacement is an effective treatment for severe aortic stenosis. Transcatheter aortic valve implantation (TAVI), also known as transcatheter aortic valve replacement (TAVR), is being evaluated as an alternative to open surgery for individuals with aortic stenosis and to nonsurgical therapy for individuals with a prohibitive risk for surgery.

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 individuals who are not surgical candidates due to excessive surgical risk, the Placement of Aortic Transcatheter Valve Trial Edwards SAPIEN

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

Transcatheter Heart Valve (PARTNER B) trial reported on results for individuals treated with TAVI by the transfemoral approach compared with continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI individuals at 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 individuals who are not surgical candidates, no randomized trials have compared the self-expandable valve with best medical therapy. However, results from the single-arm Core Valve 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 individuals 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 individuals also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk individuals have reported no major differences in rates of mortality or stroke between the 2 procedures. Since the publication of the PARTNER A trial, the Core Valve 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 individuals with intermediate-risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are OS,

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in individuals with intermediate risk for open surgery. Three of them, which included over 4000 individuals combined, reported noninferiority of TAVI versus SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of individuals (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 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 individuals randomized to open surgery and permanent pacemaker requirement higher in individuals randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon et al (2010) RCT have suggested that the benefit of TAVI may be limited to individuals who are candidates for transfemoral access. Although several RCTs have 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 individuals at low surgical risk and RCTs enrolling only low surgical risk individuals, 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 individuals who have severe, calcific, aortic stenosis requiring aortic valve replacement [PARTNER 3]) have been conducted exclusively in individuals at low surgical risk and 1 RCT, Nordic Aortic Intervention Trial included predominantly individuals 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 individuals 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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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-SAVR and have reported a reduced risk of short-term mortality (<30 days) with ViV TAVI. Beyond 30 days, meta-analyses have reported mortality outcomes that were similarly favorable or improved with redo-SAVR. The PARTNER 2 registry reported a 50.6% rate of all-cause mortality after 5 years among individuals with high surgical risk; individuals who received a 23-mm SAPIEN XT valve had a significantly higher risk of mortality compared to those who received a 26-mm valve (hazard ratio, 1.55; 95% confidence interval, 1.09 to 2.20; $p=.01$). 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 device while undergoing TAVI, the evidence includes 4 RCTs of individuals with low- to high-risk for open surgery. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. 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 individuals and did not find a significant reduction in the incidence of periprocedural stroke within 72 hours or before hospital discharge. Prior trials have generally failed to demonstrate neurocognitive protection or significant reductions in major cardiac and cerebrovascular events. Studies have not stratified results by operative risk levels and have suggested differential benefits based on valve type. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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,

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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 individuals 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 individuals 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 individuals 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

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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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
<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 individuals with severe AS and a left ventricular ejection fraction <50% (Stage C2), AVR is indicated."	I	B
"In asymptomatic individuals with severe AS (Stage C1) who are undergoing cardiac surgery for other indications, AVR is indicated."	I	B
"In symptomatic individuals with low-flow, low-gradient severe AS with reduced left ventricular ejection fraction (Stage D2), AVR is recommended."	I	B

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

"In symptomatic individuals 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 individuals 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 individuals 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 individuals 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 individuals 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 individuals 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 individuals with moderate AS (Stage B) who are undergoing cardiac surgery for other indications, AVR may be considered."	IIb	C
<i>Choice of SAVR Versus TAVI for Individuals for Whom a Bioprosthetic AVR is Appropriate</i>		
"For symptomatic and asymptomatic individuals 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 individuals 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

"For symptomatic individuals with severe AS who are >80 years of age or for younger individuals 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 individuals 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 individuals in the 3 recommendations above."	I	B
"For asymptomatic individuals 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 individuals 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 individuals 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 individuals 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 individuals with severe AS, percutaneous aortic balloon dilation may be considered as a bridge to SAVR or TAVI."	IIb	C
<i>Intervention for Prosthetic Valve Stenosis</i>		
"In individuals with symptomatic severe stenosis of a bioprosthetic or mechanical prosthetic valve, repeat surgical intervention is indicated unless surgical risk is prohibitive."	I	B

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

"For severely symptomatic individuals 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 individuals with significant bioprosthetic valve stenosis attributable to suspected or documented valve thrombosis, oral anticoagulation with a VKA is reasonable."	IIa	B
<i>Prosthetic Valve Regurgitation</i>		
"In individuals 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 individuals with severe prosthetic regurgitation and low operative risk, surgery is reasonable."	IIa	B
"In individuals with prosthetic paravalvular regurgitation with the following: 1) either intractable hemolysis or NYHA class III or IV symptoms and 2) who are at high or prohibitive surgical risk and 3) have anatomic features suitable for catheter-based therapy, percutaneous repair of paravalvular leak is reasonable when performed at a Comprehensive Valve Center."	IIa	B
"For individuals 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; LOE: level of evidence; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation; ViV: valve-in-valve; VKA: vitamin K antagonist.

National Institute for Health and Care Excellence

In June 2019, the NICE published interventional procedures guidance [IPG653] regarding valve-in-valve TAVI for aortic bioprosthetic valve dysfunction. 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

(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 individuals 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 individuals 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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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
<i>Ongoing</i>			
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 Individuals with Asymptomatic Severe Aortic Stenosis	901	Mar 2032
NCT03112980	Randomized, Multi-Center, Event-Driven Trial of TAVI versus SAVR in Individuals 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01057173	Transcatheter Versus Surgical Aortic Valve Implantation in Individuals 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
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
NCT02628899	Feasibility of Transcatheter Aortic Valve Replacement in Low-Risk Individuals with Symptomatic, Severe Aortic Stenosis	300	Jan 2023
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 Individuals 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 individuals who have severe,	1000	Dec 2029

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

NCT No.	Trial Name	Planned Enrollment	Completion Date
	calcific, aortic stenosis requiring aortic valve replacement (PARTNER 3)		

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

1. Freeman RV, Otto CM. Spectrum of calcific aortic valve disease: pathogenesis, disease progression, and treatment strategies. *Circulation*. Jun 21 2005; 111(24): 3316-26. PMID 15967862
2. Coeytaux RR, Williams JW, Gray RN, et al. Percutaneous heart valve replacement for aortic stenosis: state of the evidence. *Ann Intern Med*. Sep 07 2010; 153(5): 314-24. PMID 20679543
3. Lindroos M, Kupari M, Heikkilä J, et al. Prevalence of aortic valve abnormalities in the elderly: an echocardiographic study of a random population sample. *J Am Coll Cardiol*. Apr 1993; 21(5): 1220-5. PMID 8459080
4. Bonow RO, Carabello BA, Kanu C, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): developed in collaboration with the Society of Cardiovascular Anesthesiologists: endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. *Circulation*. Aug 01 2006; 114(5): e84-231. PMID 16880336
5. Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?. *Eur Heart J*. Dec 2005; 26(24): 2714-20. PMID 16141261
6. Lieberman EB, Bashore TM, Hermiller JB, et al. Balloon aortic valvuloplasty in adults: failure of procedure to improve long-term survival. *J Am Coll Cardiol*. Nov 15 1995; 26(6): 1522-8. PMID 7594080
7. Food and Drug Administration (FDA). Boston Scientific announces LOTUS Edge aortic valve system voluntary recall and product discontinuation. January 11, 2021.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/boston-scientific-announces-lotus-edgetm-aortic-valve-system-voluntary-recall-and-product>.

8. Food and Drug Administration (FDA). De Novo Classification Request for Sentinel Cerebral Protection System. September 19, 2016; https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN160043.pdf.
9. Food and Drug Administration (FDA). 24 Hour Summary of the Circulatory System Devices Panel Meeting - Keystone Heart, Ltd TriGUARD 3 Cerebral Embolic Protection Device. August 3, 2021; <https://www.fda.gov/media/151335/download>.
10. Aladin AI, Case BC, Wermers JP, et al. Overview of FDA Circulatory System Devices Panel virtual meeting on TriGUARD 3 cerebral embolic protection. Catheter Cardiovasc Interv. May 2022; 99(6): 1789-1795. PMID 35084082
11. Spertus J, Peterson E, Conard MW, et al. Monitoring clinical changes in patients with heart failure: a comparison of methods. Am Heart J. Oct 2005; 150(4): 707-15. PMID 16209970
12. Figulla L, Neumann A, Figulla HR, et al. Transcatheter aortic valve implantation: evidence on safety and efficacy compared with medical therapy. A systematic review of current literature. Clin Res Cardiol. Apr 2011; 100(4): 265-76. PMID 21165626
13. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. Oct 21 2010; 363(17): 1597-607. PMID 20961243
14. Reynolds MR, Magnuson EA, Lei Y, et al. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. Circulation. Nov 01 2011; 124(18): 1964-72. PMID 21969017
15. Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. May 03 2012; 366(18): 1696-704. PMID 22443478
16. Svensson LG, Blackstone EH, Rajeswaran J, et al. Comprehensive analysis of mortality among patients undergoing TAVR: results of the PARTNER trial. J Am Coll Cardiol. Jul 15 2014; 64(2): 158-68. PMID 25011720
17. Kapadia SR, Tuzcu EM, Makkar RR, et al. Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy. Circulation. Oct 21 2014; 130(17): 1483-92. PMID 25205802
18. Webb JG, Doshi D, Mack MJ, et al. A Randomized Evaluation of the SAPIEN XT Transcatheter Heart Valve System in Patients With Aortic Stenosis Who Are Not Candidates for Surgery. JACC Cardiovasc Interv. Dec 21 2015; 8(14): 1797-806. PMID 26718510

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

19. Kapadia SR, Huded CP, Kodali SK, et al. Stroke After Surgical Versus Transfemoral Transcatheter Aortic Valve Replacement in the PARTNER Trial. *J Am Coll Cardiol*. Nov 13 2018; 72(20): 2415-2426. PMID 30442284
20. Huded CP, Arnold SV, Chhatriwalla AK, et al. Rehospitalization Events After Aortic Valve Replacement: Insights From the PARTNER Trial. *Circ Cardiovasc Interv*. Dec 2022; 15(12): e012195. PMID 36538580
21. Popma JJ, Adams DH, Reardon MJ, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol*. May 20 2014; 63(19): 1972-81. PMID 24657695
22. Reardon MJ, Adams DH, Coselli JS, et al. Self-expanding transcatheter aortic valve replacement using alternative access sites in symptomatic patients with severe aortic stenosis deemed extreme risk of surgery. *J Thorac Cardiovasc Surg*. Dec 2014; 148(6): 2869-76.e1-7. PMID 25152474
23. Mack MJ, Brennan JM, Brandt's R, et al. Outcomes following transcatheter aortic valve replacement in the United States. *JAMA*. Nov 20 2013; 310(19): 2069-77. PMID 24240934
24. Yakubov SJ, Adams DH, Watson DR, et al. 2-Year Outcomes After Iliofemoral Self-Expanding Transcatheter Aortic Valve Replacement in Patients With Severe Aortic Stenosis Deemed Extreme Risk for Surgery. *J Am Coll Cardiol*. Sep 22 2015; 66(12): 1327-34. PMID 26383718
25. Baron SJ, Arnold SV, Reynolds MR, et al. Durability of quality of life benefits of transcatheter aortic valve replacement: Long-term results from the CoreValve US extreme risk trial. *Am Heart J*. Dec 2017; 194: 39-48. PMID 29223434
26. Arnold SV, Petrossian G, Reardon MJ, et al. Five-Year Clinical and Quality of Life Outcomes From the CoreValve US Pivotal Extreme Risk Trial. *Circ Cardiovasc Interv*. Jun 2021; 14(6): e010258. PMID 34092091
27. Osnabrugge RL, Arnold SV, Reynolds MR, et al. Health status after transcatheter aortic valve replacement in patients at extreme surgical risk: results from the CoreValve U.S. trial. *JACC Cardiovasc Interv*. Feb 2015; 8(2): 315-323. PMID 25700755
28. Linke A, Wenaweser P, Gerckens U, et al. Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study. *Eur Heart J*. Oct 07 2014; 35(38): 2672-84. PMID 24682842
29. Piazza N, Grube E, Gerckens U, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. *EuroIntervention*. Aug 2008; 4(2): 242-9. PMID 19110790

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

30. Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. *J Am Coll Cardiol.* Mar 16 2010; 55(11): 1080-90. PMID 20096533
31. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. *Eur Heart J.* Jan 2011; 32(2): 198-204. PMID 20864486
32. Tamburino C, Capodanno D, Ramondo A, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. *Circulation.* Jan 25 2011; 123(3): 299-308. PMID 21220731
33. Panoulas VF, Francis DP, Ruparelia N, et al. Female-specific survival advantage from transcatheter aortic valve implantation over surgical aortic valve replacement: Meta-analysis of the gender subgroups of randomised controlled trials including 3758 patients. *Int J Cardiol.* Jan 01 2018; 250: 66-72. PMID 29169764
34. Dagan M, Yeung T, Stehli J, et al. Transcatheter Versus Surgical Aortic Valve Replacement: An Updated Systematic Review and Meta-Analysis With a Focus on Outcomes by Sex. *Heart Lung Circ.* Jan 2021; 30(1): 86-99. PMID 32732125
35. Villablanca PA, Mathew V, Thourani VH, et al. A meta-analysis and meta-regression of long-term outcomes of transcatheter versus surgical aortic valve replacement for severe aortic stenosis. *Int J Cardiol.* Dec 15 2016; 225: 234-243. PMID 27732927
36. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* Jun 20 2015; 385(9986): 2477-84. PMID 25788234
37. Reardon MJ, Adams DH, Kleiman NS, et al. 2-Year Outcomes in Patients Undergoing Surgical or Self-Expanding Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol.* Jul 14 2015; 66(2): 113-21. PMID 26055947
38. Panchal HB, Ladia V, Desai S, et al. A meta-analysis of mortality and major adverse cardiovascular and cerebrovascular events following transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis. *Am J Cardiol.* Sep 15 2013; 112(6): 850-60. PMID 23756547
39. Takagi H, Niwa M, Mizuno Y, et al. A meta-analysis of transcatheter aortic valve implantation versus surgical aortic valve replacement. *Ann Thorac Surg.* Aug 2013; 96(2): 513-9. PMID 23816417

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

40. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med.* Jun 09 2011; 364(23): 2187-98. PMID 21639811
41. Reynolds MR, Magnuson EA, Wang K, et al. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A). *J Am Coll Cardiol.* Aug 07 2012; 60(6): 548-58. PMID 22818074
42. Généreux P, Cohen DJ, Williams MR, et al. Bleeding complications after surgical aortic valve replacement compared with transcatheter aortic valve replacement: insights from the PARTNER I Trial (Placement of Aortic Transcatheter Valve). *J Am Coll Cardiol.* Mar 25 2014; 63(11): 1100-9. PMID 24291283
43. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med.* May 08 2014; 370(19): 1790-8. PMID 24678937
44. Deeb GM, Reardon MJ, Chetcuti S, et al. 3-Year Outcomes in High-Risk Patients Who Underwent Surgical or Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol.* Jun 07 2016; 67(22): 2565-74. PMID 27050187
45. Zorn GL, Little SH, Tadros P, et al. Prosthesis-patient mismatch in high-risk patients with severe aortic stenosis: A randomized trial of a self-expanding prosthesis. *J Thorac Cardiovasc Surg.* Apr 2016; 151(4): 1014-22, 1023.e1-3. PMID 26614412
46. Arnold SV, Chinnakondepalli KM, Magnuson EA, et al. Five-Year Health Status After Self-expanding Transcatheter or Surgical Aortic Valve Replacement in High-risk Patients With Severe Aortic Stenosis. *JAMA Cardiol.* Jan 01 2021; 6(1): 97-101. PMID 32997095
47. Conte JV, Hermiller J, Resar JR, et al. Complications After Self-expanding Transcatheter or Surgical Aortic Valve Replacement. *Semin Thorac Cardiovasc Surg.* Autumn 2017; 29(3): 321-330. PMID 29195573
48. Gleason TG, Reardon MJ, Popma JJ, et al. 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients. *J Am Coll Cardiol.* Dec 04 2018; 72(22): 2687-2696. PMID 30249462
49. Makkar RR, Cheng W, Waksman R, et al. Self-expanding intra-annular versus commercially available transcatheter heart valves in high and extreme risk patients with severe aortic stenosis (PORTICO IDE): a randomised, controlled, non-inferiority trial. *Lancet.* Sep 05 2020; 396(10252): 669-683. PMID 32593323
50. Muneretto C, Bisleri G, Moggi A, et al. Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement. *Interact Cardiovasc Thorac Surg.* Jan 2015; 20(1): 90-5. PMID 25320140

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

51. Minutello RM, Wong SC, Swaminathan RV, et al. Costs and in-hospital outcomes of transcatheter aortic valve implantation versus surgical aortic valve replacement in commercial cases using a propensity score matched model. *Am J Cardiol.* May 15 2015; 115(10): 1443-7. PMID 25784513
52. Sedaghat A, Al-Rashid F, Sinning JM, et al. Outcome in TAVI patients with symptomatic aortic stenosis not fulfilling PARTNER study inclusion criteria. *Catheter Cardiovasc Interv.* Nov 15 2015; 86(6): 1097-104. PMID 26032437
53. Arora S, Strassle PD, Ramm CJ, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Lower Surgical Risk Scores: A Systematic Review and Meta-Analysis of Early Outcomes. *Heart Lung Circ.* Aug 2017; 26(8): 840-845. PMID 28169084
54. Arora S, Vaidya SR, Strassle PD, et al. Meta-analysis of transfemoral TAVR versus surgical aortic valve replacement. *Catheter Cardiovasc Interv.* Mar 01 2018; 91(4): 806-812. PMID 29068166
55. Garg A, Rao SV, Visveswaran G, et al. Transcatheter Aortic Valve Replacement Versus Surgical Valve Replacement in Low-Intermediate Surgical Risk Patients: A Systematic Review and Meta-Analysis. *J Invasive Cardiol.* Jun 2017; 29(6): 209-216. PMID 28570236
56. Singh K, Carson K, Rashid MK, et al. Transcatheter Aortic Valve Implantation in Intermediate Surgical Risk Patients With Severe Aortic Stenosis: A Systematic Review and Meta-Analysis. *Heart Lung Circ.* Feb 2018; 27(2): 227-234. PMID 28473216
57. Ando T, Takagi H, Grines CL. Transfemoral, transapical and transcatheter aortic valve implantation and surgical aortic valve replacement: a meta-analysis of direct and adjusted indirect comparisons of early and mid-term deaths. *Interact Cardiovasc Thorac Surg.* Sep 01 2017; 25(3): 484-492. PMID 28549125
58. Gozdek M, Raffa GM, Suwalski P, et al. Comparative performance of transcatheter aortic valve-in-valve implantation versus conventional surgical redo aortic valve replacement in patients with degenerated aortic valve bioprostheses: systematic review and meta-analysis. *Eur J Cardiothorac Surg.* Mar 01 2018; 53(3): 495-504. PMID 29029105
59. Khan SU, Lone AN, Saleem MA, et al. Transcatheter vs surgical aortic-valve replacement in low- to intermediate-surgical-risk candidates: A meta-analysis and systematic review. *Clin Cardiol.* Nov 2017; 40(11): 974-981. PMID 29168984
60. Tam DY, Vo TX, Wijeyesundera HC, et al. Transcatheter vs Surgical Aortic Valve Replacement for Aortic Stenosis in Low-Intermediate Risk Patients: A Meta-analysis. *Can J Cardiol.* Sep 2017; 33(9): 1171-1179. PMID 28843328

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

61. Witberg G, Lador A, Yahav D, et al. Transcatheter versus surgical aortic valve replacement in patients at low surgical risk: A meta-analysis of randomized trials and propensity score matched observational studies. *Catheter Cardiovasc Interv.* Aug 01 2018; 92(2): 408-416. PMID 29388308
62. Ueshima D, Fovino LN, D'Amico G, et al. Transcatheter versus surgical aortic valve replacement in low- and intermediate-risk patients: an updated systematic review and meta-analysis. *Cardiovasc Interv Ther.* Jul 2019; 34(3): 216-225. PMID 30232711
63. Levett JY, Windle SB, Filion KB, et al. Meta-Analysis of Transcatheter Versus Surgical Aortic Valve Replacement in Low Surgical Risk Patients. *Am J Cardiol.* Apr 15 2020; 125(8): 1230-1238. PMID 32089249
64. Vipparthy SC, Ravi V, Avula S, et al. Meta-Analysis of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Patients With Low Surgical Risk. *Am J Cardiol.* Feb 01 2020; 125(3): 459-468. PMID 31784051
65. Anantha-Narayanan M, Kandasamy VV, Reddy YN, et al. Low-Risk Transcatheter Versus Surgical Aortic Valve Replacement - An Updated Meta-Analysis of Randomized Controlled Trials. *Cardiovasc Revasc Med.* Apr 2020; 21(4): 441-452. PMID 31678116
66. Kundu A, Sardar P, Malhotra R, et al. Cardiovascular Outcomes with Transcatheter vs. Surgical Aortic Valve Replacement in Low-Risk Patients: An Updated Meta-Analysis of Randomized Controlled Trials. *Cardiovasc Revasc Med.* Apr 2020; 21(4): 453-460. PMID 31669113
67. Kolkailah AA, Doukky R, Pelletier MP, et al. Cochrane corner: transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis in people with low surgical risk. *Heart.* Jul 2020; 106(14): 1043-1045. PMID 32482670
68. Zhou Y, Wang Y, Wu Y, et al. Transcatheter versus surgical aortic valve replacement in low to intermediate risk patients: A meta-analysis of randomized and observational studies. *Int J Cardiol.* Feb 01 2017; 228: 723-728. PMID 27886617
69. Thyregod HG, Steinbrüchel DA, Ihlemann N, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. *J Am Coll Cardiol.* May 26 2015; 65(20): 2184-94. PMID 25787196
70. Nielsen HH, Klaaborg KE, Nissen H, et al. A prospective, randomised trial of transapical transcatheter aortic valve implantation vs. surgical aortic valve replacement in operable elderly patients with aortic stenosis: the STACCATO trial. *EuroIntervention.* Jul 20 2012; 8(3): 383-9. PMID 22581299

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

71. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med*. Apr 28 2016; 374(17): 1609-20. PMID 27040324
72. Kondur A, Briasoulis A, Palla M, et al. Meta-Analysis of Transcatheter Aortic Valve Replacement Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis. *Am J Cardiol*. Jan 15 2016; 117(2): 252-7. PMID 26639040
73. Tamburino C, Barbanti M, D'Errigo P, et al. 1-Year Outcomes After Transfemoral Transcatheter or Surgical Aortic Valve Replacement: Results From the Italian OBSERVANT Study. *J Am Coll Cardiol*. Aug 18 2015; 66(7): 804-812. PMID 26271063
74. Siemieniuk RA, Agoritsas T, Manja V, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. *BMJ*. Sep 28 2016; 354: i5130. PMID 27683246
75. Søndergaard L, Steinbrüchel DA, Ihlemann N, et al. Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement: The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial. *Circ Cardiovasc Interv*. Jun 2016; 9(6). PMID 27296202
76. Thyregod HGH, Ihlemann N, Jørgensen TH, et al. Five-Year Clinical and Echocardiographic Outcomes from the Nordic Aortic Valve Intervention (NOTION) Randomized Clinical Trial in Lower Surgical Risk Patients. *Circulation*. Feb 01 2019. PMID 30704298
77. Søndergaard L, Ihlemann N, Capodanno D, et al. Durability of Transcatheter and Surgical Bioprosthetic Aortic Valves in Patients at Lower Surgical Risk. *J Am Coll Cardiol*. Feb 12 2019; 73(5): 546-553. PMID 30732707
78. Reardon MJ, Kleiman NS, Adams DH, et al. Outcomes in the Randomized CoreValve US Pivotal High Risk Trial in Patients With a Society of Thoracic Surgeons Risk Score of 7% or Less. *JAMA Cardiol*. Nov 01 2016; 1(8): 945-949. PMID 27541162
79. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med*. Apr 06 2017; 376(14): 1321-1331. PMID 28304219
80. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. *N Engl J Med*. May 02 2019; 380(18): 1706-1715. PMID 30883053
81. Forrest JK, Deeb GM, Yakubov SJ, et al. 2-Year Outcomes After Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients. *J Am Coll Cardiol*. Mar 08 2022; 79(9): 882-896. PMID 35241222

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

82. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N Engl J Med*. May 02 2019; 380(18): 1695-1705. PMID 30883058
83. Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk. *J Am Coll Cardiol*. Mar 09 2021; 77(9): 1149-1161. PMID 33663731
84. Toff WD, Hildick-Smith D, Kovac J, et al. Effect of Transcatheter Aortic Valve Implantation vs Surgical Aortic Valve Replacement on All-Cause Mortality in Patients With Aortic Stenosis: A Randomized Clinical Trial. *JAMA*. May 17 2022; 327(19): 1875-1887. PMID 35579641
85. Jørgensen TH, Thyregod HGH, Ihlemann N, et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. *Eur Heart J*. Aug 07 2021; 42(30): 2912-2919. PMID 34179981
86. Makkar RR, Thourani VH, Mack MJ, et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. *N Engl J Med*. Feb 27 2020; 382(9): 799-809. PMID 31995682
87. Pibarot P, Salaun E, Dahou A, et al. Echocardiographic Results of Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients: The PARTNER 3 Trial. *Circulation*. May 12 2020; 141(19): 1527-1537. PMID 32272848
88. Shahim B, Malaisrie SC, George I, et al. Postoperative Atrial Fibrillation or Flutter Following Transcatheter or Surgical Aortic Valve Replacement: PARTNER 3 Trial. *JACC Cardiovasc Interv*. Jul 26 2021; 14(14): 1565-1574. PMID 34294398
89. Aedma SK, Khan N, Altamimi A, et al. Umbrella Meta-analysis Evaluating the Effectiveness of ViV-TAVI vs Redo SAVR. *SN Compr Clin Med*. Feb 26 2022; 4(63). DOI: 10.1007/s42399-022-01136-x.
90. Raschpichler M, de Waha S, Holzhey D, et al. Valve-in-Valve Transcatheter Aortic Valve Replacement Versus Redo Surgical Aortic Valve Replacement for Failed Surgical Aortic Bioprostheses: A Systematic Review and Meta-Analysis. *J Am Heart Assoc*. Dec 20 2022; 11(24): e7965. PMID 36533610
91. Sá MP, Van den Eynde J, Simonato M, et al. Late outcomes of valve-in-valve transcatheter aortic valve implantation versus re-replacement: Meta-analysis of reconstructed time-to-event data. *Int J Cardiol*. Jan 01 2023; 370: 112-121. PMID 36370873
92. National Institute For Health And Care Excellence (NICE). Interventional procedure overview of valve-in-valve TAVI for aortic bioprosthetic valve dysfunction [IPG653]. June 2019. <https://www.nice.org.uk/guidance/ipg653/evidence/overview-final-pdf-6834685357>.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

93. Phan K, Zhao DF, Wang N, et al. Transcatheter valve-in-valve implantation versus reoperative conventional aortic valve replacement: a systematic review. *J Thorac Dis.* Jan 2016; 8(1): E83-93. PMID 26904259
94. Chen HL, Liu K. Clinical outcomes for transcatheter valve-in-valve in treating surgical bioprosthetic dysfunction: A meta-analysis. *Int J Cardiol.* Jun 01 2016; 212: 138-41. PMID 27038719
95. Tam DY, Vo TX, Wijeyesundera HC, et al. Transcatheter valve-in-valve versus redo surgical aortic valve replacement for the treatment of degenerated bioprosthetic aortic valve: A systematic review and meta-analysis. *Catheter Cardiovasc Interv.* Dec 01 2018; 92(7): 1404-1411. PMID 30024102
96. Webb JG, Murdoch DJ, Alu MC, et al. 3-Year Outcomes After Valve-in-Valve Transcatheter Aortic Valve Replacement for Degenerated Bioprostheses: The PARTNER 2 Registry. *J Am Coll Cardiol.* Jun 04 2019; 73(21): 2647-2655. PMID 31146808
97. Hahn RT, Webb J, Pibarot P, et al. 5-Year Follow-Up From the PARTNER 2 Aortic Valve-in-Valve Registry for Degenerated Aortic Surgical Bioprostheses. *JACC Cardiovasc Interv.* Apr 11 2022; 15(7): 698-708. PMID 35393102
98. van Steenberghe GJ, van Straten B, Lam KY, et al. Report on outcomes of valve-in-valve transcatheter aortic valve implantation and redo surgical aortic valve replacement in the Netherlands. *Neth Heart J.* Feb 2022; 30(2): 106-112. PMID 34373997
99. Haussig S, Mangner N, Dwyer MG, et al. Effect of a Cerebral Protection Device on Brain Lesions Following Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Stenosis: The CLEAN-TAVI Randomized Clinical Trial. *JAMA.* Aug 09 2016; 316(6): 592-601. PMID 27532914
100. Van Mieghem NM, van Gils L, Ahmad H, et al. Filter-based cerebral embolic protection with transcatheter aortic valve implantation: the randomised MISTRAL-C trial. *EuroIntervention.* Jul 20 2016; 12(4): 499-507. PMID 27436602
101. Kapadia SR, Kodali S, Makkar R, et al. Protection Against Cerebral Embolism During Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol.* Jan 31 2017; 69(4): 367-377. PMID 27815101
102. Kapadia SR, Makkar R, Leon M, et al. Cerebral Embolic Protection during Transcatheter Aortic-Valve Replacement. *N Engl J Med.* Oct 06 2022; 387(14): 1253-1263. PMID 36121045
103. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

- Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Jun 10 2014; 63(22): 2438-88. PMID 24603192
104. Nishimura RA, O'Gara PT, Bonow RO. Guidelines Update on Indications for Transcatheter Aortic Valve Replacement. JAMA Cardiol. Sep 01 2017; 2(9): 1036-1037. PMID 28768333
105. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. Feb 02 2021; 77(4): e25-e197. PMID 33342586
106. National Institute For Health And Care Excellence (NICE). Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction (Interventional procedures guidance [IPG653]). June 2019. <https://www.nice.org.uk/guidance/ipg653>.
107. National Institute For Health And Care Excellence (NICE). Heart valve disease presenting in adults: investigation and management [NG208]. November 2021. <https://www.nice.org.uk/guidance/ng208/chapter/Recommendations#interventions>.
108. Centers for Medicare and Medicaid Services (CMS). Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R). <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293>.

Policy History

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

- 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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. 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

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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

Next Scheduled Review Date: 04/2024

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 2022 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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

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 Add code effective 07/01/2023: 33370
HCPCS	Add code effective 07/01/2023: C1889
ICD-10 Diagnosis	Add codes effective 08/01/2023: I06.0, I06.2, I08.0, I08.2, I08.3, I08.8, I08.9, I35.0 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;

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406

Original Effective Date: 03/19/2014

Current Effective Date: 07/01/2023

- 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.

©2023 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.