# Transcatheter Aortic Valve Implantation for Aortic Stenosis

**Policy #** 00406
Original Effective Date: 03/19/2014
Current Effective Date: 06/08/2020

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

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

# When Services Are Eligible for Coverage

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

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

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

Patient Selection Criteria

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

- Severe aortic stenosis with a calcified aortic annulus; AND
- New York Heart Association (NYHA) heart failure Class II, III or IV symptoms; AND
- Left ventricular ejection fraction greater than 20%; AND
- Patient does not have unicuspid or bicuspid aortic valves

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

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406
Original Effective Date: 03/19/2014
Current Effective Date: 06/08/2020

Patient Selection Criteria

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

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
- NYHA heart failure class II, III or IV symptoms; AND
- Left ventricular ejection fraction greater than 20%; AND
- Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery.

*Note: FDA definition of extreme risk or inoperable for open surgery is:*

- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.
- The FDA definition of high risk for open surgery is:
- Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.

*FDA definition of intermediate risk is:*

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

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

*For the use of the Sapien or CoreValve device, severe aortic stenosis is defined by the presence of one or more of the following criteria:*

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

# When Services Are Considered Investigational

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

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

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

# Background/Overview

**Aortic Stenosis**

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

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

**Disease Burden**

Aortic stenosis is a relatively common disorder in elderly patients and is the most common acquired valve disorder in the United States. Approximately 2% to 4% of people older than 65 years of age have evidence of significant aortic stenosis, increasing up to 8% of people by age 85 years. In the Helsinki Aging Study (1993), a population-based study of 501 patients, ages 75 to 86 years, the

prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%. In the United States, more than 50000 aortic valve replacements are performed annually due to severe aortic stenosis.

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

**Unmet Needs**

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

**Treatment**

Transcatheter aortic valve implantation, also known as transcatheter aortic valve replacement, has been developed in response to this unmet need and was originally intended as an alternative for patients for whom surgery was not an option due to prohibitive surgical risk or for patients at high-risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and

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

Patients with bicuspid aortic valves were excluded from randomized controlled trials (RCTs).The ongoing NOTION 2 Trial (NCT02825134) includes only patients ≤75-years-old and does not exclude patients with bicuspid aortic valves. Data collection of the primary outcome is scheduled for completion in 2020.

# FDA or Other Governmental Regulatory Approval

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

Multiple manufacturers have transcatheter aortic valve devices with 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™<br>• Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach) | Edwards Lifesciences | 11/11 | P100041 |
| • Edwards SAPIEN™ Transcatheter Heart Valve, Model 9000TFX<br>• Expanded to include high-risk aortic stenosis (transapical approach) | | 10/12 | P110021 |
| • Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories<br>• Severe native aortic valve stenosis at high or greater risk for open surgical therapy | | 07/14 | P130009 |

| | | | |
|---|---|---|---|
| • Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy | | 10/15 | P130009/S034 |
| • Expanded to include severe aortic stenosis with intermediate surgical risk | | 08/16 | P130009/S057 |
| • ·SAPIEN 3 Ultra THV System, a design iteration<br><br>Note: In August 2019, FDA issued a recall for the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System (Recall event ID: 83293) due to "reports of burst balloons which have resulted in significant difficulty retrieving the device into the sheath and withdrawing the system from the patient during procedures". | | 12/18 | P140031 |
| • ·Expanded to include severe aortic stenosis with low surgical risk | • | 08/19 | P140031/S085 |
| Medtronic CoreValve System™<br><br>• Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy | Medtronic CoreValve | 01/14 | P130021 |
| • Expanded to include high-risk for open surgical therapy | | 06/16 | P130021/S002 |
| • Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |

| | | | |
|---|---|---|---|
| • Medtronic CoreValve Evolut R System™ (design iteration for valve and accessories) | | 06/15 | P130021/S014 |
| • Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |
| • Medtronic CoreValve Evolut PRO System™ (design iteration for valve and accessories, includes porcine pericardial tissue wrap) | | 03/17 | P130021/S029 |
| • Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |
| • Expanded to include severe aortic stenosis with low surgical risk | • | 08/19 | P130021/S058 |
| • Medtronic CoreValve Evolut PRO+ Sysstem™ (design iteration) | • | 08/19 | P130021/S059 |
| LOTUS Edge™ Valve System<br>• Severe native aortic stenosis at high or greater risk for open surgical therapy | Boston Scientific Corporation | 04/19 | P180029 |

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

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

- Portico™‡ Transcatheter Aortic Valve (Abbott)
- JenaValve™‡ (JenaValve Technology); designed for transapical placement

# Rationale/Source

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

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 RCT comparing TAVI with medical management in individuals at prohibitive risk of surgery, a single-arm prospective trial, multiple case series, and multiple systematic reviews. Relevant outcomes are overall survival (OS), symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are not surgical candidates due to excessive surgical risk, the Placement of AoRTic TraNscathetER Valve Trial Edwards SAPIEN Transcatheter Heart Valve (PARTNER B) trial reported on results for patients treated with TAVI by the transfemoral approach compared with continued medical care with or without balloon valvuloplasty. There was a large decrease in mortality for the TAVI patients at 1 year compared with medical care. This trial also reported improvements in other relevant clinical outcomes for the TAVI group. There was an increased risk of stroke and vascular complications in the TAVI group. Despite these concerns, the overall balance of benefits and risks from this trial indicate that health outcomes are improved. For patients who are not surgical candidates, no randomized trials have compared the self-expandable valve with best medical therapy. However, results from the single-arm CoreValve Extreme Risk Pivotal Trial met trialists' prespecified objective performance goal. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at high-risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals at high-risk for surgery and 1 RCT comparing 2 types of valves, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are high-risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients

also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the 2 procedures. Since the publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 and 2 years for the self-expanding prosthesis. This trial reported no significant differences in stroke rates between groups. In an RCT directly comparing the self-expandable with the balloon-expandable valve among surgically high-risk patients, the devices had similar 30-day mortality outcomes, although the self-expandable valve was associated with higher rates of residual aortic regurgitation and need for a new permanent pacemaker. Evidence from RCT and nonrandomized studies has suggested that TAVI with a self-expanding device is associated with higher rates for permanent pacemakers post procedure. However, survival rates appear to be similar between device types, and the evidence does not support the superiority of one device over another in all patients. Two sex-specific studies were also identified in a literature search with the objective of observing mortality rates in women undergoing TAVI or surgical aortic valve replacement (SAVR). Results were varied, and further study is needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate-risk for open surgery who receive TAVI, the evidence includes 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate-risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in patients with intermediate-risk for open surgery. Three of them, which included over 4000 patients combined, reported noninferiority of TAVI versus SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of patients (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 2 years for TAVI versus SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs. 2%, p=0.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in patients randomized to open surgery and permanent pacemaker requirement higher in patients randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon et al (2010) RCT have suggested that the benefit of TAVI may be limited to patients who are candidates for transfemoral access. Although several RCTs have 2 years of follow-up post

procedure, it is uncertain how many individuals require reoperation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at low-risk for open surgery who receive TAVI, the evidence includes RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk and RCTs enrolling only low surgical risk patients, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs (Evolut Low Risk Trial and the Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement [PARTNER 3]) have been conducted exclusively in patients at low surgical risk and 1 RCT, Nordic Aortic Intervention Trial included predominantly patients at low surgical risk. In the Evolut Low Risk Trial, transcatheter aortic valve replacement was noninferior to SAVR with respect to the composite outcome of death or disabling stroke at 24 months. In the PARTNER 3 trial, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVI than SAVR. In the Nordic Aortic Intervention Trial, the risk of the composite outcome of death from any cause, stroke, or myocardial infarction at 5 years was similar for TAVI and SAVR and transcatheter aortic valve replacement showed less structural valve deterioration than SAVR at 6 years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have valve dysfunction and aortic stenosis or regurgitation after open surgical aortic valve repair who receive transcatheter aortic "valve-in-valve" implantation, the evidence includes observational studies including registry data with follow-up ranging from 1 month to 3 years and a systematic reviews. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Systematic reviews of observational studies have compared valve-in-valve TAVI to redo SAVR and have reported similar mortality, stroke, and survival rates for the 2 procedures. However, selection bias cannot be ruled out given that no RCTs are available. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2016 supported the use of transcatheter aortic "valve-in-valve" replacement for individuals who have degeneration of a surgically implanted aortic valve and who are at high or prohibitive risk for open repair.

# Supplemental Information

**Clinical Input from Physician Specialty Societies and Academic Medical Centers**

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

**2016 Input**

In response to requests, input was received from 2 specialty societies (1 of which provided 2 responses) and 2 academic medical centers (1 of which provided 3 responses) while this policy was under review in 2016. Although there was no support for the use of valve-in-valve transcatheter aortic valve implantation (TAVI) to replace a failed bioprosthetic valve in general use, there was general support for the use of valve-in-valve TAVI for patients at high and prohibitive risk for surgery.

**2014 Input**

In response to requests, input was received from 2 specialty societies (1 of which provided 2 responses) and 6 academic medical centers while this policy was under review in 2014. All reviewers who responded considered TAVI medically necessary for patients with severe aortic stenosis with a calcified aortic annulus and New York Heart Association functional class II, III, or IV symptoms, and who are not candidates for open surgery or who are operable candidates but are at high-risk for open surgery. Most reviewers would require a patient to have a left ventricular ejection fraction greater than 20% for the procedure to be medically necessary. All reviewers indicated support for limiting the use of TAVI to patients who are not candidates for open surgery or who are operable candidates but are at high-risk for open surgery, and most supported using the FDA definition of high-risk and extreme risk for surgery. Most reviewers noted that self-expanding valves have been associated with higher rates of post procedural pacemaker requirements but that neither type of valve was clearly superior to the other.

**2011 Input**

In response to requests, input was received from 1 specialty society and 6 academic medical centers while this policy was under review in 2011. At the time of vetting, FDA approval had not yet been granted for any TAVI device. Reviewers were mixed in support for a medically necessary indication

for patients who are not surgical candidates. However, all reviewers indicated that they would consider this procedure medically necessary if FDA granted approval. No reviewer expressed support for medical necessity in other patient populations, including patients who were at high-risk for surgery, but were surgical candidates. Concerning patient selection criteria, most reviewers referred to the study selection criteria in the PARTNER trial and did not offer further options for objective patient selection.

**Practice Guidelines and Position Statements**

American College of Cardiology and American Heart Association

In 2014, the American College of Cardiology and the American Heart Association published joint guidelines on the management of valvular heart disease. Both groups issued a joint focused update in 2017. These guidelines made the following recommendations on the choice of surgical or transcatheter intervention for treatment of aortic stenosis (see Table 2).

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

| Recommendation | COR | LOE |
|---|---|---|
| "Surgical AVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk." | I | A |
| "For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care" | I | C |
| "TAVR is recommended for symptomatic patients with severe AS and high risk for SAVR, depending on patient-specific procedural risks, values and preferences." | I | A |
| "TAVR is recommended for symptomatic patients with severe AS, prohibitive risk for SAVR and a predicted post-TAVR survival >12 mo." | I | A |
| "TAVR is a reasonable alternative to SAVR for symptomatic patients with severe AS and intermediate surgical risk, depending on patient-specific procedural risks, values and preferences" | IIa | B |
| "For severely symptomatic patients with bioprosthetic stenosis or regurgitation at high or prohibitive risk for reoperation, and in whom improvement in hemodynamics is anticipated, valve-in-valve TAVR is reasonable" | IIa | B |

| | | |
|---|---|---|
| "Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS." | IIb | C |
| "TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS." | III | B |

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

**National Institute for Health And Care Excellence**

In June 2019, the National Institute for Health and Care Excellence published interventional procedures guidance [IPG653] regarding valve-in-valve TAVI for aortic bioprosthetic valve dysfunction, The guidance was informed by an Interventional procedure overview described previously. The guidance recommendation is that "Current evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation (ViVâ€'TAVI) for aortic bioprosthetic dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit."

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

Not applicable.

**Medicare National Coverage**

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

- Device has FDA approval
- The patient (preoperatively and postoperatively) is under the care of a heart team including experienced cardiac surgeon and interventional cardiologist, who have independently examined the patient, as well as providers from other physician groups, advanced patient practitioners, nurses, research personnel and administrators
- The interventional cardiologist(s) and cardiac surgeon(s) jointly participate in the intra-operative technical aspects of TAVR
- The hospital meets qualifications for performing TAVR.

- The heart team and hospital are participating in a prospective, national, audited registry that follows patients for at least 1 year and collects specific patient, practitioner and facility level outcomes
- The registry collects necessary data and has an analysis plan to address specific questions and results are reported publicly

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

- The interventional cardiologist(s) and cardiac surgeon(s) jointly participate in the intra-operative technical aspects of TAVR
- TAVI is performed within a clinical study that has the following characteristics:
- "The clinical study must adhere to the … standards of scientific integrity and relevance to the Medicare population."
- The study must address quality of life and adverse events at follow-up periods of 1 year or longer.

**Ongoing and Unpublished Clinical Trials**

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

**Table 3. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| ***Ongoing*** | | | |
| NCT01586910[a] | Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) | 1746 (actual enrollment) | Nov 2026 |
| NCT01057173 | Transcatheter Versus Surgical Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis (NOTION) | 280 | Apr 2023 |
| NCT01240902[a] | Medtronic CoreValve® U.S. Pivotal Trial | 1453 | May 2020 |
| NCT02661451[a] | Transcatheter Aortic Valve Replacement to UNload the Left Ventricle in Patients | 300 | Mar 2020 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| | With ADvanced Heart Failure: A Randomized Trial (TAVR UNLOAD) | | |
| NCT02436655 | Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis: (AVATAR Trial): A Multicentre Randomized Controlled Trial | 312 | Sep 2022 |
| NCT01314313[a] | The PARTNER II Trial "Placement of AoRTic TraNscathetER Valves Trial" (US) [Edwards Study 2010-12] | 2032 | Nov 2024 |
| NCT02163850[a] | SALUS Trial: TranScatheter Aortic Valve RepLacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Transcatheter Aortic Valve System | 878 | Dec 2021 |
| NCT01737528 | Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry) | 16,000 | Jun 2022 |
| NCT02249000 | Safety and Clinical Performance of the Self-expanding Transcatheter BIOVALVE Prosthesis in Subjects With Severe Symptomatic Aortic Stenosis Suitable for Transfemoral Transcatheter Aortic Valve Implantation | 86 | Dec 2022 |
| NCT02628899 | Feasibility of Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic, Severe Aortic Stenosis | 300 | Jan 2023 |
| NCT02000115 | Portico Re-sheathable Transcatheter Aortic Valve System US IDE Trial | 750 | Jul 2025 |
| NCT02825134 | Nordic Aortic Valve Intervention Trial 2 - A Randomized Multicenter Comparison of Transcatheter Versus Surgical Aortic Valve | 992 | Jun 2029 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| | Replacement in Younger Low Surgical Risk Patients With Severe Aortic Stenosis (NOTION-2) | | |
| ***Unpublished*** | | | |
| NCT01645202 | A Randomized Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve Versus Edwards SAPIEN XT (The CHOICE Trial) | 240 | Dec 2018 (completed) |

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

# References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Transcatheter Aortic Valve Implantation for Aortic", 7.01.132, February 2020.
2. Freeman RV, Otto CM. Spectrum of calcific aortic valve disease: pathogenesis, disease progression, and treatment strategies. Circulation. Jun 21 2005;111(24):3316-3326. PMID 15967862
3. Coeytaux RR, Williams JW, Jr., Gray RN, et al. Percutaneous heart valve replacement for aortic stenosis: state of the evidence. Ann Intern Med. Sep 7 2010;153(5):314-324. PMID 20679543
4. Lindroos M, Kupari M, Heikkila 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):1220-1225. PMID 8459080
5. 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 1 2006;114(5):e84-231. PMID 16880336

6. 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):2714-2720. PMID 16141261
7. 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):1522-1528. PMID 7594080
8. Spertus J, Peterson E, Conard MW, et al. Monitoring clinical changes in patients with heart failure: a comparison of methods.. Am. Heart J., 2005 Oct 8;150(4). PMID 16209970
9. 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- 276. PMID 21165626
10. 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):1597-1607. PMID 20961243
11. 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 1 2011;124(18):1964-1972. PMID 21969017
12. Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. May 3 2012;366(18):1696-1704. PMID 22443478
13. 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):158-168. PMID 25011720
14. 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):1483-1492. PMID 25205802
15. 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):1797-1806. PMID 26718510
16. 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., 2018 Nov 18;72(20). PMID 30442284

17. 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):1972-1981. PMID 24657695
18. 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):2869-2876 e2861-2867. PMID 25152474
19. Mack MJ, Brennan JM, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the United States. JAMA. Nov 20 2013;310(19):2069-2077. PMID 24240934
20. 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):1327-1334. PMID 26383718
21. 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
22. 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
23. 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 7 2014;35(38):2672-2684. PMID 24682842
24. 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):242-249. PMID 19110790
25. Rodes-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):1080-1090. PMID 20096533
26. 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
27. 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

28. 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 1 2018;250:66-72. PMID 29169764
29. 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
30. 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. 2016 Dec 15;225:234-243. doi: 10.1016/j.ijcard.2016.10.003. Epub 2016 Oct 6. PubMed PMID: 27732927
31. 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):2477-2484. PMID 25788234
32. 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):113-121. PMID 26055947
33. 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):850-860. PMID 23756547
34. 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):513-519. PMID 23816417
35. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. Jun 9 2011;364(23):2187-2198. PMID 21639811
36. 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 7 2012;60(6):548-558. PMID 22818074
37. Genereux 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):1100-1109. PMID 24291283
38. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med. May 8 2014;370(19):1790-1798. PMID 24678937
39. 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 7 2016;67(22):2565-2574. PMID 27050187
40. Zorn GL, 3rd, 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- 1022, 1023 e1011-1013. PMID 26614412
41. Conte JV, Hermiller J, Jr., 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
42. 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., 2018 Sep 27;72(22). PMID 30249462
43. Food and Drug Administration. Summary Of Safety And Effectiveness Data (SSED): LOTUS EdgeTM Valve System. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180029B.pdf.
44. Reardon MJ, Feldman TE, Meduri CU, et al. Two-Year Outcomes After Transcatheter Aortic Valve Replacement With Mechanical vs Self-expanding Valves: The REPRISE III Randomized Clinical Trial.. JAMA Cardiol, 2019 Feb 28;4(3). PMID 30810703
45. 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):90-95. PMID 25320140
46. 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):1443-1447. PMID 25784513
47. 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):1097-1104. PMID 26032437
48. 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

49. Arora S, Vaidya SR, Strassle PD, et al. Meta-analysis of transfemoral TAVR versus surgical aortic valve replacement. Catheter Cardiovasc Interv. Oct 25 2017. PMID 29068166
50. 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
51. 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
52. 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 1 2017;25(3):484-492. PMID 28549125
53. 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 1 2018;53(3):495-504. PMID 29029105
54. 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
55. Tam DY, Vo TX, Wijeysundera 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
56. 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. Feb 1 2018. PMID 29388308
57. 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, 2018 Sep 21;34(3). PMID 30232711
58. 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. Nov 12 2016;228:723-728. PMID 27886617
59. Thyregod HG, Steinbruchel 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):2184-2194. PMID 25787196
60. 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):383-389. PMID 22581299
61. 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):1609-1620. PMID 27040324
62. 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- 257. PMID 26639040
63. 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
64. 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
65. Sondergaard L, Steinbruchel 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
66. Thyregod HGH, Ihlemann N, Jorgensen 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, 2019 Feb 2. PMID 30704298
67. Sondergaard L, Ihlemann N, Capodanno D, Jrgensen TH, Nissen H, Kjeldsen BJ, Chang Y, Steinbrchel DA, Olsen PS, Petronio AS, Thyregod HGH. Durability of Transcatheter and Surgical Bioprosthetic Aortic Valves in Patients at Lower Surgical Risk. J Am Coll Cardiol. 2019 Feb 12;73(5):546-553. PMID: 30732707.
68. 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 1 2016;1(8):945-949. PMID 27541162
69. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. Apr 6 2017;376(14):1321-1331. PMID 28304219

70. 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., 2019 Mar 19;380(18). PMID 30883053
71. 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., 2019 Mar 19;380(18). PMID 30883058
72. National Institute For Health And Care Excellence. Interventional procedure overview of valve-in-valve TAVI for aortic bioprosthetic valve dysfunction (IP 1013/2 [IPG653]). June 2019. https://www.nice.org.uk/guidance/ipg653/evidence/overview-final-pdf-6834685357.
73. Phan K, Zhao DF, Wang N, Huo YR, Di Eusanio M, Yan TD. Transcatheter valve-in-valve implantation versus reoperative conventional aortic valve replacement: a systematic review. J Thorac Dis. 2016 Jan;8(1):E83-93. PMID: 26904259
74. Chen HL, Liu K. Clinical outcomes for transcatheter valve-in-valve in treating surgical bioprosthetic dysfunction: A meta-analysis. Int J Cardiol. 2016 Jun 1;212:138-41. Epub 2016 Mar 18. PMID: 27038719.
75. Tam DY, Vo TX, Wijeysundera HC, Dvir D, Friedrich JO, Fremes SE. 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. 2018 Dec 1;92(7):1404-1411. Epub 2018 Jul 19. PMID: 30024102.
76. 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 Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Jun 10 2014;63(22):2438-2488. PMID 24603192
77. Nishimura RA, O'Gara PT, Bonow RO. Guidelines update on indications for transcatheter aortic valve replacement. JAMA Cardiol. Sep 1 2017;2(9):1036-1037. PMID 28768333
78. National Institute For Health And Care Excellence.Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction, Interventional procedures guidance [IPG653]. June 2019. https://www.nice.org.uk/guidance/ipg653.
79. Centers for Medicaid and Medicare Services. Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R). https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293&bc=ACAAAAAAQAAA&.

Policy # 00406
Original Effective Date: 03/19/2014
Current Effective Date: 06/08/2020

# Policy History

Original Effective Date: 03/19/2014
Current Effective Date: 06/08/2020

| | |
|---|---|
| 03/06/2014 | Medical Policy Committee review |
| 03/19/2014 | Medical Policy Implementation Committee approval. New policy. |
| 03/05/2015 | Medical Policy Committee review |
| 03/20/2015 | Medical Policy Implementation Committee approval. Added "FDA approved" to the eligible for coverage statement. Updated rationale/source and references. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 03/05/2015 | Medical Policy Committee review |
| 03/20/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 05/05/2016 | Medical Policy Committee review |
| 05/18/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 11/03/2016 | Medical Policy Committee review |
| 11/16/2016 | Medical Policy Implementation Committee approval. Added coverage statement for valve in valve for patient at high or prohibitive risk for open surgery. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 05/04/2017 | Medical Policy Committee review |
| 05/17/2017 | Medical Policy Implementation Committee approval. Added "native valve" to coverage statement. |
| 06/07/2018 | Medical Policy Committee review |
| 06/20/2018 | Medical Policy Implementation Committee approval. Policy statements changed to add patients at intermediate surgical risk to first eligible for coverage statement. |
| 08/14/2018 | Coding update |
| 06/06/2019 | Medical Policy Committee review |
| 06/19/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 03/05/2020 | Medical Policy Committee review |
| 03/11/2020 | Medical Policy Implementation Committee approval. Eligible for coverage policy statement related to patients with native valve aortic stenosis changed to add an |

| | |
|---|---|
| | exclusion for patients with unicuspid or bicuspid aortic valve and to add an inclusion for patients at low risk for open surgery.<br>Removed "Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high or intermediate risk for open surgery." From criteria section. |
| 7/20/2020 | Updated coverage criteria statement |

Next Scheduled Review Date: 03/2021

# 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 2019 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.

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406
Original Effective Date: 03/19/2014
Current Effective Date: 06/08/2020

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

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

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

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

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

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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

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

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

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