Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy #  00406
Original Effective Date:  03/19/2014
Current Effective Date:  06/19/2019

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.

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 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.

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 to be eligible for coverage.**
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Patient Selection Criteria
Coverage eligibility will be met for transcatheter aortic valve replacement (TAVR) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve 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 high risk for open surgery:

- 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%.

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 cm²
- An aortic valve area index of less than or equal to 0.6 cm²/m²
- 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.*
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The use of transcatheter aortic valve replacement (TAVR) when patient selection criteria are not met is considered to be investigational.*

Policy Guidelines
The U.S. Food and Drug Administration (FDA) definition of extreme risk or inoperable for open surgery is:
• Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.

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

The FDA definition of intermediate risk is:
• Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.

For the use of the SAPIEN or CoreValve devices, severe aortic stenosis is defined by the presence of one or more of the following criteria:
• An aortic valve area of less than or equal to 1 cm2
• An aortic valve area index of less than or equal to 0.6 cm2/m2
• 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.

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 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.
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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 primarily surgical, involving replacement of the diseased valve with a bioprosthetic or mechanical valve by open heart surgery.

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 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

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

Unmet Needs
Many patients with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of patients presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities. For patients who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes. Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction, and aortic regurgitation. Also, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in patients at increased risk for open surgery.
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**Treatment**
Transcatheter aortic valve implantation has been developed in response to this unmet need and was originally intended as an alternative for patients for whom surgery was not an option due to prohibitive surgical risk or for patients at high risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass.

**FDA or Other Governmental Regulatory Approval**

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

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

<table>
<thead>
<tr>
<th>Device and Indication</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>PMA</th>
</tr>
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<tbody>
<tr>
<td>Edwards SAPIEN Transcatheter Heart Valve System™</td>
<td>Edwards Lifesciences</td>
<td>11/11</td>
<td>P100041</td>
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<tr>
<td>• Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Expanded to include high-risk aortic stenosis (transapical approach)</td>
<td></td>
<td>10/12</td>
<td></td>
</tr>
<tr>
<td>• Expanded to include replacement of bioprosthetic valve in high risk for death or severe complications of repeat surgery</td>
<td></td>
<td>06/17</td>
<td></td>
</tr>
<tr>
<td>• Expanded to include severe aortic stenosis with intermediate surgical risk</td>
<td></td>
<td>08/16</td>
<td></td>
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<table>
<thead>
<tr>
<th>Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories</th>
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<tbody>
<tr>
<td>• Severe native aortic valve stenosis at high or greater risk for open surgical therapy</td>
</tr>
<tr>
<td>• Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy</td>
</tr>
<tr>
<td>• Expanded to include severe aortic stenosis with intermediate surgical risk</td>
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<table>
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<tr>
<th>Medtronic CoreValve System™‡</th>
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<tr>
<td>• Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy</td>
</tr>
<tr>
<td>• Expanded to include high risk for open surgical therapy</td>
</tr>
<tr>
<td>• Expanded to include intermediate risk for open surgical therapy</td>
</tr>
<tr>
<td>Medtronic CoreValve</td>
</tr>
<tr>
<td>01/14 P130021</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Medtronic CoreValve Evolut R System™‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Design iteration for valve and accessories</td>
</tr>
<tr>
<td>• Expanded to include intermediate risk for open surgical therapy</td>
</tr>
<tr>
<td>06/15 P130021/S014</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medtronic CoreValve Evolut PRO System™+</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Design iteration for valve and accessories (includes porcine pericardial tissue wrap)</td>
</tr>
<tr>
<td>• Expanded to include intermediate risk for open surgical therapy</td>
</tr>
<tr>
<td>03/17 P130021/S029</td>
</tr>
</tbody>
</table>

Medtronic CoreValve Evolut PRO System™+

FDA: Food and Drug Administration; PMA: post market approval.
Other transcatheter aortic valve systems are under development. The following repositionable valves are under investigation:

- **Lotus™‡ Aortic Valve Replacement System (Boston Scientific)**
- **Portico™ Transcatheter Aortic Valve (St. Jude Medical)**
- **JenaValve™‡ (JenaValve Technology); designed for transapical placement**

On June 1, 2017, the FDA cleared the Sentinel®‡ Cerebral Protection System (Claret Medical Inc. and Boston Scientific) which is indicated for use as an embolic protection device to capture and remove thrombus and tissue debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 – 10 mm in the left common carotid. The device received a de novo classification as a class II device (DEN 160043). The FDA order, therefore, classifies the Sentinel®‡ Cerebral Protection System, and substantially equivalent devices of this generic type, into class II under the generic name, temporary catheter for embolic protection during transcatheter intra cardiac procedures.

Several additional embolic protection devices have been under investigation; TriGuard and Embrella.

**Rationale/Source**

Transcatheter aortic valve implantation (TAVI; also known as transcatheter aortic valve replacement) is a potential treatment for patients with severe aortic stenosis. Many patients with aortic stenosis are elderly and/or have multiple medical comorbidities, thus indicating a high, often prohibitive, risk for surgery. This procedure is being evaluated as an alternative to open surgery, or surgical aortic valve replacement (SAVR), for high-risk patients with aortic stenosis and as an alternative 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 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, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are not surgical candidates due to excessive surgical risk, the 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’ pre-specified 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, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, 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 non-inferiority 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 vs 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 non-inferiority 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 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.
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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 overall survival, 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 non-inferiority of TAVI vs 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 vs 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 RCT has 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 2 RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Limited data are available comparing SAVR with TAVI in patients who had severe aortic stenosis with low risk for open surgery. A systematic review including the low surgical risk patients of these 2 RCTs, and 4 observational studies, with propensity score matching, reported that the 30-day and in-hospital mortality rates were similar for TAVI (2.2%) and SAVR (2.6%). However, TAVI was associated with increased risk of mortality with longer follow-up (median, 2 years; 17.2% vs 12.7%). TAVI was associated with reduced risk for bleeding, renal failure and, an increase in vascular complications and pacemaker implantation compared with SAVR. The evidence is insufficient to determine the effects of the technology on health outcomes.
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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 case series (largest with 459 patients) and systematic reviews of case series. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. These case series have reported high rates of technical success of valve implantation and improvement in heart failure symptoms for most patients. However, they have also reported high rates of short-term complications and high rates of mortality at 1 year post-procedure. There is a lack of evidence comparing valve-in-valve replacement with alternative treatment approaches. 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 (one of which provided 2 responses) and 2 academic medical centers (one 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 (one 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 Food and Drug Administration’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.

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
The American College of Cardiology and the American Heart Association (2014) 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

<table>
<thead>
<tr>
<th>Recommendation</th>
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<th>LOE</th>
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<tbody>
<tr>
<td>“Surgical AVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk.”</td>
<td>I</td>
<td>A</td>
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“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.”

“TAVR is recommended for symptomatic patients with severe AS and high risk for SAVR, depending on patient-specific procedural risks, values and preferences.”

“TAVR is recommended for symptomatic patients with severe AS, prohibitive risk for SAVR and a predicted post-TAVR survival >12 mo.”

“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.”

“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”

“Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS.”

“TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS.”


References
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...
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the PARTNER (Placement of AoRTic TranScathetER Valve) Trial (Cohort A). J Am Coll Cardiol. Aug 7 2012;60(6):548-558. PMID 22818074
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Policy History
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03/06/2014 Medical Policy Committee review
03/19/2014 Medical Policy Implementation Committee approval. New policy.
03/05/2015 Medical Policy Committee review
03/20/2015 Medical Policy Implementation Committee approval. Added “FDA approved” to the eligible for coverage statement. Updated rationale/source and references.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/05/2015 Medical Policy Committee review
03/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2016 Medical Policy Committee review
05/18/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2016 Medical Policy Committee review
11/16/2016 Medical Policy Implementation Committee approval. Added coverage statement for valve in valve for patient at high or prohibitive risk for open surgery.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017 Medical Policy Committee review
05/17/2017 Medical Policy Implementation Committee approval. Added “native valve” to coverage statement.
06/07/2018 Medical Policy Committee review
06/20/2018 Medical Policy Implementation Committee approval. Policy statements changed to add patients at intermediate surgical risk to first eligible for coverage statement.
08/14/2018 Coding update
06/06/2019 Medical Policy Committee review
06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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Next Scheduled Review Date: 06/2020

**Coding**

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

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<th>Code Type</th>
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</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>106.0-106.9, 108.0, 108.8-108.9, 135.0-135.9</td>
</tr>
</tbody>
</table>

*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.
Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy # 00406
Original Effective Date: 03/19/2014
Current Effective Date: 06/19/2019

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.