Introduction

The aortic valve is a valve that separates the main pumping chamber of the heart (the left ventricle) from the large artery that takes oxygen rich blood away from the heart and out to the body (the aorta). If the valve doesn’t completely open, it is called aortic stenosis. Aortic stenosis decreases the amount of oxygenated blood getting out to the body. Open surgery is one method of replacing a damaged aortic valve. A newer procedure — known as transcatheter aortic valve replacement or transcatheter aortic valve implantation — has been developed. It allows a replacement valve to be threaded through an artery and into the heart without open heart surgery. A catheter (a long thin tube) is threaded through an artery, either in the leg or in the chest, and into the heart. The replacement valve is then lodged into the defective aortic valve. The new valve is then expanded, pushing aside parts of the old valve. This policy describes when transcatheter aortic valve replacement may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Transcatheter aortic valve replacement        | Transcatheter aortic valve replacement with a U.S. Food and Drug Administration (FDA)–approved transcatheter heart valve system, when performed via an approach consistent with the device’s FDA-approved labeling, may be considered medically necessary as a treatment for native valve aortic stenosis when ALL of the following criteria are met:  
  - Severe aortic stenosis (see the Definition of Terms section) with a calcified aortic annulus is present  
  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 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high or intermediate risk for open surgery (see the Definition of Terms section) |
| Transcatheter aortic valve replacement        | Transcatheter aortic valve replacement with an FDA approved transcatheter heart valve system for repair of a degenerated bioprosthetic valve may be considered medically necessary when ALL of the following criteria are met:  
  - 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 (see the Definition of Terms section) |
Transcatheter aortic valve replacement is considered investigational for all other indications and when criteria are not met.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
</tr>
<tr>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
</tr>
<tr>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
</tr>
<tr>
<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
</tr>
<tr>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)</td>
</tr>
<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)</td>
</tr>
<tr>
<td>33367</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>33368</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>33369</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Definition of Terms

**Extreme risk or inoperable for open heart surgery:** FDA definition of extreme risk or inoperable for open surgery:

- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery

**High Risk for open heart surgery:** 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

**Intermediate risk:** FDA definition of intermediate risk is:

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

**Severe aortic stenosis:** 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

Evidence Review
Description

Transcatheter aortic valve implantation (TAVI; also known as transcatheater 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.

Background

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.\(^1\) Congenital abnormalities of the aortic valve, most commonly a bicuspid valve, increase the risk for 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.\(^1\) 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 and syncope often occur and the disorder progresses rapidly. Treatment of aortic stenosis is primarily surgical, involving replacement of the diseased valve with a bio-prosthetic 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,\(^1\) increasing up to 8% of people by age 85 years.\(^2\) 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 periods of up to 20 years. However, these benefits are accompanied by a 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 (MI), 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 who are at increased risk for open surgery.

**Treatment**

Transcatheter aortic valve implantation (TAVI) 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 the need for cardiopulmonary bypass.
Summary of Evidence

For individuals who have severe symptomatic aortic stenosis who are at prohibitive risk for open surgery who receive transcatheter aortic valve implantation (TAVI), the evidence includes a randomized controlled trial (RCT) comparing TAVI with medical management in individuals at prohibitive risk of surgery, a single-arm prospective trial, multiple case series, and multiple systematic reviews. Relevant outcomes are overall survival, 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 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 publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 year 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 requirement 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 postprocedure. However, survival rates appear to be similar between device types, and the evidence does not clearly 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.

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 noninferiority 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 postprocedure, 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. For individuals who have valve dysfunction and aortic stenosis or regurgitation after aortic valve repair who receive transcatheter aortic “valve-in-valve” implantation, the evidence includes case series (largest included 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 postprocedure. 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01586910</td>
<td>Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI)</td>
<td>2500</td>
<td>Oct 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT02956915</td>
<td>Evaluation of Length of Stay and Predisposing Factors of Late Discharge After Transfemoral Transcatheter Aortic Valve Implantation Using the SAPIEN-3 Prosthesis: A French Multicenter Prospective Observational Trial</td>
<td>300</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT01057173</td>
<td>Transcatheter Versus Surgical Aortic Valve Implantation in Patients With Severe Aortic Valve Stenosis (NOTION)</td>
<td>280</td>
<td>Apr 2018</td>
</tr>
<tr>
<td>NCT01645202</td>
<td>A Randomized Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve Versus Edwards SAPIEN XT (The CHOICE Trial)</td>
<td>240</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT01240902</td>
<td>Medtronic CoreValve® U.S. Pivotal Trial</td>
<td>1650</td>
<td>Aug 2019</td>
</tr>
<tr>
<td>NCT02661451</td>
<td>Transcatheter Aortic Valve Replacement to UNload the Left Ventricle in Patients With ADvanced Heart Failure: A Randomized Trial (TAVR UNLOAD)</td>
<td>600</td>
<td>May 2020</td>
</tr>
<tr>
<td>NCT02436655</td>
<td>Aortic Valve Replacement Versus Conservative Treatment in</td>
<td>312</td>
<td>Jun 2020</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT01314313</td>
<td>Asymptomatic Severe Aortic Stenosis: (AVATAR Trial): A Multicentre Randomized Controlled Trial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02163850</td>
<td>The PARTNER II Trial “Placement of AoRTic TranScathetER Valves Trial” (US) [Edwards Study 2010-12]</td>
<td>6650</td>
<td>Sep 2020</td>
</tr>
<tr>
<td>NCT01737528</td>
<td>SALUS Trial: TranScatheter Aortic Valve RepLacement System Pivotal Trial The Safety and Effectiveness of the Direct Flow Medical Transcatheter Aortic Valve System</td>
<td>878</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT01737528</td>
<td>Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry)</td>
<td>16,000</td>
<td>Jun 2022</td>
</tr>
<tr>
<td>NCT02249000</td>
<td>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</td>
<td>86</td>
<td>Dec 2022</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

\* Denotes industry-sponsored or cosponsored trial.

**Clinical Input Received 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, clinical input was received from 2 specialty societies (1 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 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, clinical 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 provided a response 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, clinical 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 the 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 make the following recommendations regarding 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>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>“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”</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>“TAVR is recommended for symptomatic patients with severe AS and high risk for SAVR, depending on patient-specific procedural risks, values and preferences.”</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>“TAVR is recommended for symptomatic patients with severe AS, prohibitive risk for SAVR and a predicted post-TAVR survival &gt;12 mo.”</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>“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”</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>“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”</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>“Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS.”</td>
<td>IIb</td>
<td>C</td>
</tr>
<tr>
<td>“TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS.”</td>
<td>III</td>
<td>B</td>
</tr>
</tbody>
</table>

The European Society for Cardiology and the European Association for Cardio-Thoracic Surgery (2017) published joint guidelines on the management of valvular heart disease. These guidelines made the following recommendations on the use of TAVI (see Table 3).

Table 3. Recommendations on Surgical or Transcatheter Intervention for Aortic Stenosis

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.”</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>In patients who are at increased surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥10% or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics, with TAVI being favoured in elderly patients suitable for transfemoral access.”</td>
<td>I</td>
<td>B</td>
</tr>
</tbody>
</table>


U.S. Preventive Services Task Force Recommendations

Transcatheter aortic valve implantation is not a preventive service.

Medicare National Coverage

The Centers for Medicare & Medicaid Services (CMS) published a decision memo on the use of transcatheter aortic valve replacement (TAVR) in 2012. This memo indicated that CMS covers TAVI when used according to FDA indications when the following conditions are met:

- Device has FDA approval
- Two cardiac surgeons agree with indications for the procedure
- The patient is “under the care of a heart team”, and the hospital meets qualifications for performing TAVR.
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:

- 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.

**Regulatory Status**

Two manufacturers have transcatheter aortic valve devices with Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in **Table 4**.

**Table 4. 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>
</thead>
<tbody>
<tr>
<td>Edwards SAPIEN Transcatheter Heart Valve System™</td>
<td>Edwards Lifesciences</td>
<td>11/11</td>
<td>P100041</td>
</tr>
<tr>
<td>- Severe native aortic valve stenosis determined to be inoperable for open aortic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>
</tr>
<tr>
<td>Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories</td>
<td></td>
<td>07/14</td>
<td>P130009</td>
</tr>
<tr>
<td>- Severe native aortic valve stenosis at high or greater risk for open surgical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Expanded to include failure of bioprosthetic valve in high or greater risk for</td>
<td></td>
<td>10/15</td>
<td>P130009/S034</td>
</tr>
<tr>
<td>open surgical therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device and Indication</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>PMA</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td>--------------</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>
</tr>
<tr>
<td>Medtronic CoreValve System™</td>
<td>Medtronic CoreValve</td>
<td>01/14</td>
<td>P130021</td>
</tr>
<tr>
<td>- Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Expanded to include high risk for open surgical therapy</td>
<td></td>
<td>06/16</td>
<td>P130021/ S002</td>
</tr>
<tr>
<td>- Expanded to include intermediate risk for open surgical therapy</td>
<td></td>
<td>07/17</td>
<td>P130021/ S033</td>
</tr>
<tr>
<td>Medtronic CoreValve Evolut R System™</td>
<td></td>
<td>06/15</td>
<td>P130021/ S014</td>
</tr>
<tr>
<td>- Design iteration for valve and accessories</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Expanded to include intermediate risk for open surgical therapy</td>
<td></td>
<td>07/17</td>
<td>P130021/ S033</td>
</tr>
<tr>
<td>Medtronic CoreValve Evolut PRO System™</td>
<td></td>
<td>03/17</td>
<td>P130021/ S029</td>
</tr>
<tr>
<td>- Design iteration for valve and accessories</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Expanded to include intermediate risk for open surgical therapy</td>
<td></td>
<td>07/17</td>
<td>P130021/ S033</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: postmarket 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

Several embolic protection devices, which are designed to collect embolic debris distal to the transcatheter aortic valve implantation apparatus and to prevent ischemic stroke, are under investigation. No devices have FDA approval for use in the United States. Examples include the TriGuard (Keystone Heart) and the Sentinel Cerebral Protection System (Claret Medical).
References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/11/13</td>
<td>Replace policy. Policy updated with literature review, references 7, 15, 16, 18, 20, 23–28, 30 added. Medically necessary indications added for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach. Investigational statement added for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in-Valve approach), and for vascular approaches other than transfemoral or transapical. Codes updated.</td>
</tr>
<tr>
<td>12/23/13</td>
<td>Coding Update. Add new CPT 33366, effective 01/01/14; 0318T discontinued effective 12/31/13; deleted codes 0256T – 0259T removed.</td>
</tr>
<tr>
<td>02/10/14</td>
<td>Replace policy. Policy updated with literature review through November 15, 2013. References 8, 18, 19, 22, 23, 27 added. Policy statement revised to include medically necessary indication for TAVI by the transapical approach for patients who are not suitable candidates for open surgery. ICD-10 Procedure codes 35.05 and 35.22 removed from the policy; they were provided for informational purposes only.</td>
</tr>
<tr>
<td>12/17/14</td>
<td>Annual Review. Policy statement revised to remove statement that “procedures performed via the transaxillary, transiliac, transaortic, or other approaches” are investigational, to reflect the approval of the CoreValve device that is labeled for use via transaxillary, transfemoral, and transaortic approaches. Policy statement added stating that devices should be used according to their FDA approved indication. Clinical input supported proposed policy statements. Policy updated with literature review through September 1, 2014, and the results of clinical input. References 9–10, 15–17, 23, 28–34, 36, 41–43, 45, 47, 49–52, 57–59 added; others renumbered/removed. Policy statements changed as noted. ICD-9 and ICD-10 diagnosis and procedure codes removed; these do not relate to policy adjudication.</td>
</tr>
<tr>
<td>02/01/16</td>
<td>Coding update. Added 93799.</td>
</tr>
<tr>
<td>10/24/17</td>
<td>Policy moved to new format; no change to policy statements.</td>
</tr>
</tbody>
</table>
**Disclaimer**: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):

Oromoo (Cushite):

Deutsche (German):

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期，您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Français (French):
Premera Blue Cross.

Este aviso contém informações importantes.

Este aviso contém informações importantes privind cererá ou acoperiria assegurári

dunmeavostrae de sântate pre Premera Blue Cross. Po exista date chée

in acéetá notificáre. Este posiv sé fie nevoie s aktionári pre la unmiti
termes limitées para a wènt acoperirea aségurierâ de sântate sau

asisténa prívitoare la costuri. Avei dreptul de a obține gratuit aceste

ifi ajutor în limba dunmeavostră. Sunați la 800-722-1471

(TTY: 800-842-5357).

조사 (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa

na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o

pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang

petsa dito sa paunawa. Maaring paunawa na ito ay maaaring naglalaman ng

mahalagang impormasyon.

(b) (Vietnamese):

Thông báo này. Quý vâ

tham gia ho

và cung cấp thêm thông tin này và được trợ giúp bằng ngôn ngữ của mình

để. Quy vi có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình

để. Quy vi có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình

để.