MEDICAL POLICY – 7.01.132
Transcatheter Aortic Valve Implantation for Aortic Stenosis

BCBSA Ref. Policy: 7.01.132
Effective Date: May 1, 2017
Last Revised: Oct. 24, 2017
Replaces: N/A

RELATED MEDICAL POLICIES:
7.01.131 Transcatheter Pulmonary Valve Implantation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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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  
  <br>  AND  
  - New York Heart Association (NYHA) heart failure class II, III or IV symptoms  
  <br>  AND  
  - Left ventricular ejection fraction greater than 20%  
  <br>  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).  
  <br>  
  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  
  <br>  AND  
  - NYHA heart failure class II, III or IV symptoms  
  <br>  AND  
  - Left ventricular ejection fraction greater than 20%  
  <br>  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).  
  <br>  |
Procedure | Medical Necessity
--- | ---
 | Terms section).
 | Transcatheter aortic valve replacement is considered investigational when criteria are not met.

Additional Information

Transcatheter aortic valve implantation (TAVI) is also known as transcatheter aortic valve replacement (TAVR). This procedure is a potential alternative treatment for patients with severe aortic stenosis who may be high-risk candidates for open-heart aortic valve replacement (SAVR) surgery.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<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>
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<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
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<tr>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)</td>
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<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>
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<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>Code</td>
<td>Description</td>
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<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).

### Related Information

#### 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

**Severe aortic stenosis:** For the use of the Sapien or CoreValve device, severe aortic stenosis is defined by the presence of 1 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
Description

Many patients with aortic stenosis are elderly and/or have multiple medical comorbidities, thus indicating a high, often prohibitive, risk for surgery. TAVR or TAVI procedure is an alternative to open surgery 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. 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. 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. Aortic stenosis is primarily treated by doing open heart surgery to replace the diseased valve with a bio-prosthetic or mechanical valve.

Burden of Illness

Aortic stenosis is a relatively common disorder of elderly patients and is the most common acquired valve disorder in the U.S. 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.
the Helsinki Aging Study, a population-based study of 501 patients aged 75 to 86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%. In the United States, more than 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

Aortic stenosis does not cause substantial morbidity or mortality when the disease is mild or moderate in severity. By the time it reaches the severe stage, 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. In addition, 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.

Transcatheter Aortic Valve Implantation (TAVI)

TAVI has been developed in response to the unmet needs described earlier and is intended as an alternative treatment for patients in whom open surgery is not an option due to a high or prohibitive surgical risk. 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.

There are at least two transcatheter aortic valve devices being used. The Edwards SAPIEN transcatheter heart-valve system™ (Edwards Lifesciences, Irvine, CA) is a tri-leaflet bioprosthetic porcine valve that is contained within a stainless steel frame. This device first received FDA approval in 2011, with expanded indications for approval granted in 2012 and 2013.

The CoreValve ReValving System and the second-generation Evolut R system are porcine bioprosthetic valves sewn within a self-expanding nitinol frame, which received FDA approval in 2014. The CoreValve is most commonly inserted via the transfemoral artery approach, but can also be inserted via a non-iliofemoral approach (subclavian artery or direct aortic access). The Evolut R system incorporates a repositionable valve and an in-line catheter design, reducing the diameter of the device delivery system.7

Several embolic protection devices, which are designed to collect embolic debris distal to the TAVI apparatus and to prevent ischemic stroke, are under investigation. None of these devices have FDA approval for use in the United States. Examples include the TriGuard (Keystone Heart, Caesarea, Israel) and the Sentinel Cerebral Protection System (Claret Medical, Santa Rosa, CA).

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 1 randomized controlled trial (RCT) comparing TAVI with medical management in individuals at prohibitive risk of surgery, and multiple case series. 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 results for patients treated with TAVI by the transfemoral approach compared to 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 on 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 the authors’ pre-specified objective performance goal. The evidence is sufficient to determine
qualitatively 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 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 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 1 device over another in all patients. The evidence is sufficient to determine qualitatively 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 or intermediate 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. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. One investigator-initiated RCT reported no significant difference in the composite rates of death, stroke, or myocardial infarction at 1 year between patients treated with TAVI or with open surgical repair. 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. A second study was terminated early due to unexpectedly high rates of adverse events in the TAVI arm; it did not report any data on efficacy outcomes. Further RCT evidence in this population is needed to determine the efficacy of TAVI compared to surgery, to better define the early adverse event rate, and to determine whether TAVI is as good as surgery in the longer term. 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>
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<td><strong>Onngoing</strong></td>
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<tr>
<td>NCT02202434¹</td>
<td>REPRISE III: Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus™ Valve System – Randomized Clinical Evaluation</td>
<td>1032</td>
<td>Jan 2017</td>
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<td>NCT01586910¹</td>
<td>Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI)</td>
<td>2500</td>
<td>Oct 2017</td>
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<td>NCT01982032</td>
<td>Edwards SAPIEN Periprosthetic Leakage Evaluation Versus Medtronic CoreValve in Transfemoral Aortic Valve Implantation (the ELECT Trial)</td>
<td>108</td>
<td>Nov 2017</td>
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<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>
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<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>
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<tr>
<td>NCT01240902¹</td>
<td>Medtronic CoreValve® U.S. Pivotal Trial</td>
<td>1650</td>
<td>Aug 2019</td>
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<tr>
<td>NCT02661451¹</td>
<td>Transcatheter Aortic Valve Replacement to UNload the Left Ventricle in Patients With ADvanced Heart Failure: A</td>
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<td>May 2020</td>
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<td>NCT No.</td>
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<td>NCT02436655</td>
<td>Aortic Valve Replacement Versus Conservative Treatment in Asymptomatic Severe Aortic Stenosis: (AVATAR Trial): A Multicentre Randomized Controlled Trial</td>
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<td>NCT01314313a</td>
<td>The PARTNER II Trial “Placement of AoRTic TranScathetER Valves Trial” (US) [Edwards Study 2010-12]</td>
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<td>NCT02163850a</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>
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</table>

NCT: national clinical trial.

*a 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 provide appropriate reviewers who collaborate with and make recommendations during this process, 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 (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 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 operable 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 operable 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. None of the reviewers 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**

In 2014, the American Heart Association and the American College of Cardiology published guidelines for the management of valvular heart disease. These guidelines make the following recommendations regarding the choice of surgical or transcatheter intervention for treatment of aortic stenosis:

- **Class I recommendations:**
  - Surgical AVR [aortic valve replacement] is recommended in patients who meet an indication for AVR with low or intermediate surgical risk (Level of Evidence: A).
For patients in whom TAVR [transcatheter aortic valve replacement] or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care (Level of Evidence: C).

TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12mo (Level of Evidence: B).

- **Class IIa recommendations:**
  - TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR and who have high surgical risk (Level of Evidence: B).

- **Class IIb recommendations:**
  - Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS (Level of Evidence: C).

- **Class III recommendations (no benefit):**
  - TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS (Level of Evidence: B).

**European Society for Cardiology and the European Association for Cardio-Thoracic Surgery**

In 2012, the European Society for Cardiology and the European Association for Cardio-Thoracic Surgery published guidelines for the management of valvular heart disease. These guidelines make the following recommendations regarding the use of TAVI:

- **Class I recommendations:**
  - TAVI should only be undertaken with a multidisciplinary ‘heart team’ including cardiologists and cardiac surgeons and other specialists if necessary (Level of Evidence: C).
  - TAVI should only be performed in hospitals with cardiac surgery on-site (Level of Evidence: C).
  - TAVI is indicated in patients with severe symptomatic AS [aortic stenosis] who are not suitable for AVR [aortic valve replacement] as assessed by a ‘heart team’ and who are
likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities (Level of Evidence: B).

- Class IIa recommendations:
  - TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a ‘heart team’ based on the individual risk profile and anatomic suitability (Level of Evidence: B).

**American College of Cardiology Foundation and the Society of Thoracic Surgeons**

A “Professional Society Overview” on transcatheter valve therapy was published July 2011 by the American College of Cardiology Foundation and the Society of Thoracic Surgeons. The purpose of this document was to enumerate the core issues that will be anticipated in integrating TAVI into general clinical care. As part of this document, a list of necessary components for the successful introduction of Transcatheter Heart Valve Therapies was developed:

- Specialized heart centers with experienced multidisciplinary physicians and paramedical personnel

- Professional multidisciplinary heart team:
  - Primary cardiologists
  - Cardiac surgeons
  - Interventional cardiologists
  - Echocardiographers and imaging specialists
  - Heart failure specialists

- Proper procedure and facilities
  - Modified conventional cardiac laboratory
  - Hybrid operating room

- Development of and participation in clinical database and registries
Knowledge of, and evaluation of, evidence-based medical literature concerning patient selection, procedural performance, and complication management

Specific standardized protocols for management strategies, procedural performance, problem-solving, and complication management

“Appropriate ongoing personnel training”

U.S. Preventive Services Task Force Recommendations

Transcatheter aortic valve implantation is not a preventive service.

Medicare National Coverage

The Centers for Medicare and Medicaid Services published a decision memo on the use of transcatheter aortic valve replacement in May 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 (CED) program. The following is a summary of the main conditions required for CED:

- 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 AEs at follow-up periods of 1 year or longer.
Regulatory Status

**SAPIEN Transcatheter Heart Valve System**

In November 2011, the SAPIEN Transcatheter Heart Valve System™ (Edwards LifeSciences, Irvine, CA) was originally approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for patients with severe aortic stenosis who are not eligible for open-heart procedures and have a calcified aortic annulus. Approval was granted for both the transfemoral and transapical approach. For the transfemoral approach, patient indications were broadened to include patients at high risk for open surgery. For the transapical approach, approval was granted for patients at high risk for open surgery. In September 2012, the FDA expanded the indications for the transapical approach to include both inoperable patients and patients at high risk for open surgery. As a result, the SAPIEN Transcatheter Heart Valve System™ is approved for both high-risk and inoperable patients when used by either the transapical or transfemoral approach. In June 2014, the next-generation SAPIEN XT Transcatheter Heart Valve (model 9300TFX) was approved by the FDA for use with the NovaFlex+ delivery system. In October 2015, the FDA expanded the indication for the SAPIEN valve to include treatment of a failed surgical bioprosthesis (TAV-in-SAV or “valve-in-valve”).

**SAPIEN XT Valve System and Introducers**

In August 2016, the SAPIEN XT valve and introducers were approved with an expanded indication to include individuals at intermediate surgical risk for open aortic valve replacement (ie, predicted risk of surgical mortality ≥3% at 30 days based on the Society of Thoracic Surgeons [STS] Risk Score and other clinical comorbidities unmeasured by the STS Risk Calculator). The earlier generation Sapien devices also received the expanded indication for intermediate surgical risk patients.

**CoreValve® Transcatheter Aortic Valve Replacement System**

In January 2014, the CoreValve® Transcatheter Aortic Valve Replacement System (Medtronic, Minneapolis, MN) was approved by the FDA through the premarket approval process for patients with symptomatic heart disease due to severe native calcific aortic stenosis and with native aortic annulus diameters between 18 and 29 mm who are judged by a heart team, including a cardiac surgeon, to be at extreme risk or inoperable for open surgical therapy. In June 2014, the FDA expanded the indications for the CoreValve® to include patients at high risk
for open surgery. FDA labeling indicates that the device can be delivered via femoral, subclavian/axillary, or ascending aortic access.11 In March 2015, the FDA further expanded the indications for the CoreValve® to include treatment of a failed surgical bioprosthesis (TAV-in-SAV or "valve-in-valve").12 A second-generation CoreValve® device, the CoreValve Evolut™ R System, received FDA approval in June 2015.

Systems are under development. Other transcatheter aortic valve systems under development include:

- The Lotus™ Aortic Valve Replacement System (Boston Scientific, Marlborough, MA) is another repositionable valve that incorporates an outer seal to reduce paravalvular regurgitation. It has been evaluated in single-arm studies.13
- Portico™ Transcatheter Aortic Valve (St. Jude Medical, St. Paul, MN)
- The JenaValve™ (JenaValve Technology, Munich) is a repositionable valve designed for transapical placement that has been evaluated in single-arm studies.14,15
- Direct Flow Medical Transcatheter Aortic Valve System (Direct Flow Medical, Santa Rosa, CA).

References


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<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/27/12</td>
<td>New Policy – Add to Surgery section. Policy created with literature search through October 2011; considered medically necessary for patients who are not surgical candidates; investigational for all other indications.</td>
</tr>
<tr>
<td>09/27/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<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>Date</td>
<td>Comments</td>
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<td>-----------</td>
<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>05/01/17</td>
<td>Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 22, 2016; references 20, 31-34, 45, 48-55, and 85 added. Policy statements unchanged.</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). ©2017 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 425-918-5992, TTY 800-842-5357
Email AppealsDepartmentinquines@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 S909, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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):

يحتوي هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة يهمك أو تتعلق بـ Premera Blue Cross 3611 معلومات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعددة الملفات، معلومات تتعلق بـ Premera Blue Cross متعدد

Oromo (Cushite):


Français (French):


Kreyòl ayisyen (Creole):

Avi sila a gen enfòmasyon enpòtan ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsènan apektasayon w lan oswa kon kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék akson avan sèten dat limit pou ka kertre kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewka enfòmasyon sa a ak asirans lan lang ou pale a, san ou pa gen pou peyey sa ou. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):


Hmong (Hmong):


Ilokano (Ilocano):

Daytoy a pakdaara ket naglao ini Napatge nga Impormasion. Daytoy a pakdaara mabalin nga adda ket naglao ini napatge nga impormasion maipanggep iti aplikasyono weny coverage banaan ini Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaara. Mabalin nga adda rumbang nga aramidenyo nga adda sabbay dagiti partikular a naituging nga adda sidawa tapno mapataginaldeyo ti coverage ti salan-ayyo weny tungol kadagiit gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tungol iti bukodyo a pagasasao nga awan ti bayadanoy. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Premera Blue Cross. There may be important information in this notice about your application or coverage that you need to know. You may call 800-722-1471 (TTY: 800-842-5357) for more information.

This notice contains important information. To obtain more information, call 800-722-1471 (TTY: 800-842-5357).