Medical Policy
Transcatheter Aortic Valve Implantation for Aortic Stenosis

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Policy Number: 392
BCBSA Reference Number: 7.01.132
NCD/LCD: National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32)

Related Policies
- Transcatheter Pulmonary Valve Implantation, #403

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Transcatheter aortic valve replacement with an FDA-approved transcatheter heart valve system, performed via an approach consistent with the device’s FDA-approved labeling may be MEDICALLY NECESSARY 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 risk for open surgery.

Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve may be considered MEDICALLY NECESSARY when all of the following conditions are present:
- Failed (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.
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 extreme risk or inoperable for open surgery:
- Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.

For the use of the Sapien or CoreValve device, severe aortic stenosis is defined by the presence of one or more of the following criteria:
- An aortic valve area of less than or equal to 1 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.

Transcatheter aortic valve replacement is considered INVESTIGATIONAL for all other indications.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

**Nationally Covered Indications**

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:

TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:

1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.
2. Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.
3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

In addition to these patient criteria, facilities must meet established CMS criteria. For a full description of **facility qualifications** for a TAVR program, please refer to the NCD.

**National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR)**
(20.32)

**Prior Authorization Information**

Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>N/A</td>
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</table>
Medicare HMO BlueSM | N/A
---|---
Medicare PPO BlueSM | N/A

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
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<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>
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</table>

### ICD-9 Procedure Codes

<table>
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<tr>
<th>ICD-9-CM procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>35.05</td>
<td>Endovascular replacement of aortic valve</td>
</tr>
<tr>
<td>35.22</td>
<td>Open and other replacement of aortic valve</td>
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ICD-10 Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>02RF0JZ</td>
<td>Replacement Of Aortic Valve With Synthetic Substitute, Open Approach</td>
</tr>
<tr>
<td>02RF3JZ</td>
<td>Replacement Of Aortic Valve With Synthetic Substitute, Percutaneous Approach</td>
</tr>
<tr>
<td>02RF4JZ</td>
<td>Replacement Of Aortic Valve With Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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Description

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/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.

Burden of Illness
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, 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 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 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, 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 at increased risk for open surgery.
Transcatheter Aortic Valve Implantation

Transcatheter aortic valve implantation has been developed in response to this unmet need and is intended as an alternative for patients in whom surgery is not an option due to prohibitive surgical risk or for patients who are 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.

Two transcatheter aortic valve devices have Food and Drug Administration (FDA) approval. The Edwards SAPIEN Transcatheter Heart Valve System is a tri-leaflet bioprosthetic porcine valve contained within a stainless steel frame. This device first received FDA approval in 2011, with expanded indications 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.

Summary

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 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 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’ prespecified 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 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 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.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>3/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>3/2015</td>
<td>BCBSA National medical policy review. Removed 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. A statement was added to the policy statement that devices should be used according to their FDA approved indication. Effective 3/1/2015.</td>
</tr>
<tr>
<td>1/2014</td>
<td>Updated to add new CPT code 33366 and removed deleted code 0318T.</td>
</tr>
<tr>
<td>6/2013</td>
<td>BCBSA National medical policy review.</td>
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</table>
New medically necessary and investigational indications described. Effective 6/1/2013.

11/1/2012 New policy describing ongoing coverage and non-coverage.

Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


