

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy Transcatheter Aortic Valve Implantation for Aortic Stenosis

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References

Policy Number: 392

Authorization Information

BCBSA Reference Number: 7.01.132 (For Plan internal use only)

Related Policies

Transcatheter Pulmonary Valve Implantation, #403

Policy

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

Transcatheter aortic valve replacement with a U.S. Food and Drug Administration (FDA)–approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling, may be considered <u>MEDICALLY NECESSARY</u> for individuals 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 heart failure class II, III, or IV symptoms; AND
- Left ventricular ejection fraction greater than 20%; AND
- Individual does not have unicuspid or bicuspid aortic valves.

Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) may be considered <u>MEDICALLY</u> <u>NECESSARY</u> 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
- Individual is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); or individual is an operable candidate but is at high risk* for open surgery.

*The FDA definition of high risk for open surgery is:

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

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

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

*The FDA definition of intermediate risk is:

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

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

*For the use of the Sapien or CoreValve 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.

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

Use of a cerebral embolic protection device (e.g., Sentinel) during transcatheter aortic valve replacement procedures is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.

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

CPT Codes

CPT codes:	
	Code Description
	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve;
33361	percutaneous femoral artery approach

	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open
33362	femoral artery approach
	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open
33363	axillary artery approach
	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac
33364	artery approach
	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic
33365	approach (eg, median sternotomy, mediastinotomy)
	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical
33366	exposure (eg, left thoracotomy)
	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
33367	procedure)
	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
33368	procedure)
	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
33369	procedure)

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
02RF0JZ	Replacement of Aortic Valve with Synthetic Substitute, Open Approach
02RF3JZ	Replacement of Aortic Valve with Synthetic Substitute, Percutaneous Approach
02RF4JZ	Replacement of Aortic Valve with Synthetic Substitute, Percutaneous Endoscopic Approach

The following CPT code is considered investigational for <u>Commercial Members: Managed Care</u> (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	
	Code Description
	Transcatheter placement and subsequent removal of cerebral embolic protection
	device(s), including arterial access, catheterization, imaging, and radiological
	supervision and interpretation, percutaneous (List separately in addition to code for
33370	primary procedure)

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.¹ Congenital abnormalities of the aortic valve, most commonly a bicuspid or unicuspid valve, increase the risk of aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia.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/syncope often occur, and the disorder progresses rapidly. Treatment of aortic stenosis is replacement of the diseased valve with a bioprosthetic or mechanical valve.

Disease Burden

Aortic stenosis is a relatively common disorder in elderly patients and is the most common acquired valve disorder in the United States. Approximately 2% to 4% of people older than 65 years of age have evidence of significant aortic stenosis,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 aged 75 to 86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%.³ 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.⁴. Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for up to 20 years.⁴. However, these benefits are accompanied by perioperative mortality of approximately 3% to 4% and substantial morbidity,⁴. 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.⁵. 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.⁶. Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction, and aortic regurgitation. Also, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in patients at increased risk for open surgery.

Treatment

Transcatheter aortic valve implantation, also known as transcatheter aortic valve replacement, has been developed in response to this unmet need and was originally intended as an alternative for patients for whom surgery was not an option due to prohibitive surgical risk or for patients at high-risk for open surgery. The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastino scopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass.

Summary

Description

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

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

For individuals who have severe symptomatic aortic stenosis who are at high-risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals at high-risk for surgery and 1 RCT comparing 2 types of valves, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are high-risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the 2 procedures. Since the publication of the PARTNER A trial, the CoreValve High Risk Trial demonstrated noninferiority for survival at 1 and 2 years for the self-expanding prosthesis. This trial reported no significant differences in stroke rates between groups. An RCT directly comparing the Portico valve with other United States Food and Drug Administration (FDA)-approved valves found an increase in safety outcomes with Portico at 30 days but no major differences at 2 years. Gender-specific meta-analyses have found improved mortality with TAVI compared with surgical aortic valve replacement (SAVR) in women. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate-risk for open surgery who receive TAVI, the evidence includes 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate-risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in patients with intermediate-risk for open surgery. Three of them, which included over 4000 patients combined, reported noninferiority of TAVI versus SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of patients (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 2 years for TAVI versus SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs. 2%, p=.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in patients randomized to open surgery and permanent pacemaker requirement higher in patients randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon et al (2010) RCT have suggested that the benefit of TAVI may be limited to patients who are candidates for transfemoral access. Although several RCTs have 2 years of follow-up postprocedure, it is uncertain how many individuals require reoperation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at low-risk for open surgery who receive TAVI, the evidence includes RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk and RCTs enrolling only low surgical risk patients, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are OS,

symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs (Evolut Low Risk Trial and the Study to Establish the Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients Who Have Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement [PARTNER 3]) have been conducted exclusively in patients at low surgical risk and 1 RCT, Nordic Aortic Intervention Trial included predominantly patients at low surgical risk. In the Evolut Low Risk Trial, transcatheter aortic valve replacement was noninferior to SAVR with respect to the composite out come of death or disabling stroke at 24 months. In the PARTNER 3 trial, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVI than SAVR. In the Nordic Aortic Intervention Trial, the risk of the composite outcome of death from any cause, stroke, or myocardial infarction at 5 years was similar for TAVI and SAVR and transcatheter aortic valve replacement showed less structural valve deterioration than SAVR at 6 years. In the publicly sponsored UK TAVI trial, which was conducted in patients aged 70 years or older with predominantly low surgical risk, TAVI was noninferior to SAVR with respect to all-cause mortality at 1 year. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have valve dysfunction and aortic stenosis or regurgitation after open surgical aortic valve repair who receive transcatheter aortic "valve-in-valve" (ViV) implantation, the evidence includes observational studies including registry data with follow-up ranging from 1 month to 5 years and systematic reviews. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Recent meta-analyses of observational studies have compared ViV TAVI to redo-SAVR and have reported a reduced risk of short-term mortality (<30 days) with ViV TAVI. Beyond 30 days, meta-analyses have reported mortality outcomes that were similarly favorable or improved with redo-SAVR. The PARTNER 2 registry reported a 50.6% rate of all-cause mortality after 5 years among patients with high surgical risk; patients who received a 23-mm SAPIEN XT valve had a significantly higher risk of mortality compared to those who received a 26-mm valve (hazard ratio, 1.55; 95% confidence interval, 1.09 to 2.20; p=.01). Given that no RCTs are available, selection bias cannot be ruled out. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic aortic stenosis who receive a cerebral embolic protection device while undergoing TAVI, the evidence includes 4 RCTs of patients with low- to high-risk for open surgery. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Three RCTs have primarily focused on the number and/or volume of new brain lesions detected on magnetic resonance imaging with unclear correlations to neurocognitive outcomes. Only 1 of these trials (CLEAN-TAVI) found a significant reduction in brain lesion number; however, the relevance of this trial is limited as it used a precursor to the currently marketed Sentinel device. The largest and most recent trial (PROTECTED TAVR) enrolled 3000 patients and did not find a significant reduction in the incidence of periprocedural stroke within 72 hours or before hospital discharge. Prior trials have generally failed to demonstrate neurocognitive protection or significant reductions in major cardiac and cerebrovascular e vents. Studies have not stratified results by operative risk levels and have suggested differential benefits based on valve type. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Date	Action
7/2023	Annual policy review. Policy revised. Investigational policy statement added for use of cerebral embolic protection devices in individuals undergoing TAVI. Minor editorial refinements to existing policy statements; intent unchanged. Clarified coding information. Effective 7/1/2023.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.

Policy History

1	
6/2020	Annual policy review. Medically Necessary policy statement related to patients with native valve aortic stenosis changed to add an exclusion for patients with unicuspid or bicuspid aortic valve and to add an inclusion for patients at low risk for open surgery. Effective 6/1/2020.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2018	Annual policy review. Policy statements revised to add patients at intermediate surgical risk to first medically necessary statement. Clarified coding information. Effective 9/1/2018.
3/2017	New references added from Annual policy review.
1/2017	Annual policy review. Medically necessary policy statement added for valve-in-valve implantation in patients at high or prohibitive risk for open surgery. Effective 1/1/2017.
3/2015	Annual 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.
5/2014	Annual policy review. New medically necessary indications described. Effective 5/1/2014.
1/2014	Updated to add new CPT code 33366 and removed deleted code 0318T.
6/2013	Annual policy review. 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

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