MASSACHUSETTS

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

Table of Contents

Policy Number: 392

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 **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 heart failure class II, III, or IV symptoms; **AND**
- Left ventricular ejection fraction greater than 20%; **AND**
- Patient 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 **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.

*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%.

Patients 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 cm^2
- An aortic valve area index of less than or equal to 0.6 cm^2/m^2
- 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.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient
- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	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 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

CPT codes:	Code Description
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach

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

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

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, ages 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 50000 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 mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass.

Diversity, Equity, and Inclusion in Aortic Stenosis

Recent literature has identified potential differences in access, uptake, and outcomes of TAVI based on patient-specific factors including race, gender, socioeconomic status, or age. Registry data indicate that between 2011 and 2015 over 90% of patients undergoing TAVI were White.[7] At this time, causative factors for this disparity appear to be multifactorial but are poorly defined. The American College of Cardiology has categorized barriers to management of aortic stenosis as patient-related (e.g., patient refusal, insurance, social demographics), healthcare system related (e.g., cultural awareness, provider-patient relationship), and disease-related (e.g., aortic stenosis severity, left ventricular function, comorbidities).[8] They have proposed 4 basic strategies to improve treatment disparity in patients with aortic stenosis including: utilization of measure-based quality improvement programs to identify inequality and improve treatment; provision of culturally competent communication and team-based care; improvement in health care access, education, and diagnosis in underserved communities; and enhancement of research in minorities and reporting of race and ethnicity data.

Summary

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 (also known as transcatheter aortic valve replacement) 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.

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 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 (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 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' 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. In an RCT directly comparing the self-expandable with the balloon-expandable valve among surgically high-risk patients, the devices had similar 30-day mortality outcomes, although the self-expandable valve was associated with higher rates of residual aortic regurgitation and need for a new permanent pacemaker. Evidence from RCT and nonrandomized studies has suggested that TAVI with a self-expanding device is associated with higher rates for permanent pacemakers postprocedure. However, survival rates appear to be similar between device types, and the evidence does not support the superiority of 1 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 surgical aortic valve replacement (SAVR). Results were varied, and further study is needed. 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=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(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 outcome 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. 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” implantation, the evidence includes observational studies including registry data with follow-up ranging from 1 month to 3 years and a systematic reviews. Relevant outcomes are OS, symptoms, morbid events, and treatment-related mortality and morbidity. Systematic reviews of observational studies have compared valve-in-valve TAVI to redo SAVR and have reported similar mortality, stroke, and survival rates for the 2 procedures. However, selection bias cannot be ruled out given that no RCTs are available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
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.
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

References

1. Freeman RV, Otto CM. Spectrum of calcific aortic valve disease: pathogenesis, disease progression, and treatment strategies. Circulation. Jun 21 2005; 111(24): 3316-26. PMID 15967862
2. Coeytaux RR, Williams JW, Gray RN, et al. Percutaneous heart valve replacement for aortic stenosis: state of the evidence. Ann Intern Med. Sep 07 2010; 153(5): 314-24. PMID 20679543
3. Lindroos M, Kupari M, Heikkila J, et al. Prevalence of aortic valve abnormalities in the elderly: an echocardiographic study of a random population sample. J Am Coll Cardiol. Apr 1993; 21(5): 1220-5. PMID 8459080
4. Bonow RO, Carabello BA, Kanu C, et al. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): developed in collaboration with the Society of Cardiovascular Anesthesiologists: endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. Circulation. Aug 01 2006; 114(5): e84-231. PMID 16880336
5. Iung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery?. Eur Heart J. Dec 2005; 26(24): 2714-20. PMID 16141261
6. Lieberman EB, Bashore TM, Hermiller JB, et al. Balloon aortic valvuloplasty in adults: failure of procedure to improve long-term survival. J Am Coll Cardiol. Nov 15 1995; 26(6): 1522-8. PMID 7594080
7. Alkhouli M, Holmes DR, Carroll JD, et al. Racial Disparities in the Utilization and Outcomes of TAVR: TVT Registry Report. JACC Cardiovasc Interv. May 27 2019; 12(10): 936-948. PMID 31122351
8. Batchelor W, Anwaruddin S, Ross L, et al. Aortic Valve Stenosis Treatment Disparities in the Underserved: JACC Council Perspectives. J Am Coll Cardiol. Nov 05 2019; 74(18): 2313-2321. PMID 31672188
9. Food and Drug Administration. Boston Scientific announces LOTUS Edge aortic valve system voluntary recall and product discontinuation. January 11, 2021. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/boston-scientific-announces-lotus-edgetm-aortic-valve-system-voluntary-recall-and-product?utm_medium=email&utm_source=govdelivery. Accessed December 27, 2021.
10. Spertus J, Peterson E, Conard MW, et al. Monitoring clinical changes in patients with heart failure: a comparison of methods. Am Heart J. Oct 2005; 150(4): 707-15. PMID 16209970
11. Figulla L, Neumann A, Figulla HR, et al. Transcatheter aortic valve implantation: evidence on safety and efficacy compared with medical therapy. A systematic review of current literature. Clin Res Cardiol. Apr 2011; 100(4): 265-76. PMID 21165626
12. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. Oct 21 2010; 363(17): 1597-607. PMID 20961243

13. Reynolds MR, Magnuson EA, Lei Y, et al. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. Circulation. Nov 01 2011; 124(18): 1964-72. PMID 21969017
14. Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. May 03 2012; 366(18): 1696-704. PMID 22443478
15. Svensson LG, Blackstone EH, Rajeswaran J, et al. Comprehensive analysis of mortality among patients undergoing TAVR: results of the PARTNER trial. J Am Coll Cardiol. Jul 15 2014; 64(2): 158-68. PMID 25011720
16. Kapadia SR, Tuzcu EM, Makkar RR, et al. Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy. Circulation. Oct 21 2014; 130(17): 1483-92. PMID 25205802
17. Webb JG, Doshi D, Mack MJ, et al. A Randomized Evaluation of the SAPIEN XT Transcatheter Heart Valve System in Patients With Aortic Stenosis Who Are Not Candidates for Surgery. JACC Cardiovasc Interv. Dec 21 2015; 8(14): 1797-806. PMID 26718510
18. Kapadia SR, Huded CP, Kodali SK, et al. Stroke After Surgical Versus Transfemoral Transcatheter Aortic Valve Replacement in the PARTNER Trial. J Am Coll Cardiol. Nov 13 2018; 72(20): 2415-2426. PMID 30442284
19. Popma JJ, Adams DH, Reardon MJ, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. J Am Coll Cardiol. May 20 2014; 63(19): 1972-81. PMID 24657695
20. Reardon MJ, Adams DH, Coselli JS, et al. Self-expanding transcatheter aortic valve replacement using alternative access sites in symptomatic patients with severe aortic stenosis deemed extreme risk of surgery. J Thorac Cardiovasc Surg. Dec 2014; 148(6): 2869-76.e1-7. PMID 25152474
21. Mack MJ, Brennan JM, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the United States. JAMA. Nov 20 2013; 310(19): 2069-77. PMID 24240934
22. Yakubov SJ, Adams DH, Watson DR, et al. 2-Year Outcomes After Iliofemoral Self-Expanding Transcatheter Aortic Valve Replacement in Patients With Severe Aortic Stenosis Deemed Extreme Risk for Surgery. J Am Coll Cardiol. Sep 22 2015; 66(12): 1327-34. PMID 26383718
23. Baron SJ, Arnold SV, Reynolds MR, et al. Durability of quality of life benefits of transcatheter aortic valve replacement: Long-term results from the CoreValve US extreme risk trial. Am Heart J. Dec 2017; 194: 39-48. PMID 29223434
24. Arnold SV, Petrossian G, Reardon MJ, et al. Five-Year Clinical and Quality of Life Outcomes From the CoreValve US Pivotal Extreme Risk Trial. Circ Cardiovasc Interv. Jun 2021; 14(6): e010258. PMID 34092091
25. Osnabrugge RL, Arnold SV, Reynolds MR, et al. Health status after transcatheter aortic valve replacement in patients at extreme surgical risk: results from the CoreValve U.S. trial. JACC Cardiovasc Interv. Feb 2015; 8(2): 315-323. PMID 25700755
26. Linke A, Wenaweser P, Gerckens U, et al. Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study. Eur Heart J. Oct 07 2014; 35(38): 2672-84. PMID 24682842
27. Piazza N, Grube E, Gerckens U, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. EuroIntervention. Aug 2008; 4(2): 242-9. PMID 19110790
28. Rodes-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol. Mar 16 2010; 55(11): 1080-90. PMID 20096533
29. Zahn R, Gerckens U, Grube E, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. Eur Heart J. Jan 2011; 32(2): 198-204. PMID 20864486
30. Tamburino C, Capodanno D, Ramondo A, et al. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. Circulation. Jan 25 2011; 123(3): 299-308. PMID 21220731
31. Panoulas VF, Francis DP, Ruparelia N, et al. Female-specific survival advantage from transcatheter aortic valve implantation over surgical aortic valve replacement: Meta-analysis of the gender

subgroups of randomised controlled trials including 3758 patients. Int J Cardiol. Jan 01 2018; 250: 66-72. PMID 29169764
32. Dagan M, Yeung T, Stehli J, et al. Transcatheter Versus Surgical Aortic Valve Replacement: An Updated Systematic Review and Meta-Analysis With a Focus on Outcomes by Sex. Heart Lung Circ. Jan 2021; 30(1): 86-99. PMID 32732125
33. Villablanca PA, Mathew V, Thourani VH, et al. A meta-analysis and meta-regression of long-term outcomes of transcatheter versus surgical aortic valve replacement for severe aortic stenosis. Int J Cardiol. Dec 15 2016; 225: 234-243. PMID 27732927
34. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet. Jun 20 2015; 385(9986): 2477-84. PMID 25788234
35. Reardon MJ, Adams DH, Kleiman NS, et al. 2-Year Outcomes in Patients Undergoing Surgical or Self-Expanding Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. Jul 14 2015; 66(2): 113-21. PMID 26055947
36. Panchal HB, Ladia V, Desai S, et al. A meta-analysis of mortality and major adverse cardiovascular and cerebrovascular events following transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis. Am J Cardiol. Sep 15 2013; 112(6): 850-60. PMID 23756547
37. Takagi H, Niwa M, Mizuno Y, et al. A meta-analysis of transcatheter aortic valve implantation versus surgical aortic valve replacement. Ann Thorac Surg. Aug 2013; 96(2): 513-9. PMID 23816417
38. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. Jun 09 2011; 364(23): 2187-98. PMID 21639811
39. Reynolds MR, Magnuson EA, Wang K, et al. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A). J Am Coll Cardiol. Aug 07 2012; 60(6): 548-58. PMID 22818074
40. Genereux P, Cohen DJ, Williams MR, et al. Bleeding complications after surgical aortic valve replacement compared with transcatheter aortic valve replacement: insights from the PARTNER I Trial (Placement of Aortic Transcatheter Valve). J Am Coll Cardiol. Mar 25 2014; 63(11): 1100-9. PMID 24291283
41. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med. May 08 2014; 370(19): 1790-8. PMID 24678937
42. Deeb GM, Reardon MJ, Chetcuti S, et al. 3-Year Outcomes in High-Risk Patients Who Underwent Surgical or Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. Jun 07 2016; 67(22): 2565-74. PMID 27050187
43. Zorn GL, Little SH, Tadros P, et al. Prosthesis-patient mismatch in high-risk patients with severe aortic stenosis: A randomized trial of a self-expanding prosthesis. J Thorac Cardiovasc Surg. Apr 2016; 151(4): 1014-22, 1023.e1-3. PMID 26614412
44. Arnold SV, Chinnakondepalli KM, Magnuson EA, et al. Five-Year Health Status After Self-expanding Transcatheter or Surgical Aortic Valve Replacement in High-risk Patients With Severe Aortic Stenosis. JAMA Cardiol. Jan 01 2021; 6(1): 97-101. PMID 32997095
45. Conte JV, Hermiller J, Resar JR, et al. Complications After Self-expanding Transcatheter or Surgical Aortic Valve Replacement. Semin Thorac Cardiovasc Surg. Autumn 2017; 29(3): 321-330. PMID 29195573
46. Gleason TG, Reardon MJ, Popma JJ, et al. 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients. J Am Coll Cardiol. Dec 04 2018; 72(22): 2687-2696. PMID 30249462
47. Makkar RR, Cheng W, Waksman R, et al. Self-expanding intra-annular versus commercially available transcatheter heart valves in high and extreme risk patients with severe aortic stenosis (PORTICO IDE): a randomised, controlled, non-inferiority trial. Lancet. Sep 05 2020; 396(10252): 669-683. PMID 32593323
48. Muneretto C, Bisleri G, Moggi A, et al. Treating the patients in the 'grey-zone' with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement. Interact Cardiovasc Thorac Surg. Jan 2015; 20(1): 90-5. PMID 25320140

49. Minutello RM, Wong SC, Swaminathan RV, et al. Costs and in-hospital outcomes of transcatheter aortic valve implantation versus surgical aortic valve replacement in commercial cases using a propensity score matched model. Am J Cardiol. May 15 2015; 115(10): 1443-7. PMID 25784513
50. Sedaghat A, Al-Rashid F, Sinning JM, et al. Outcome in TAVI patients with symptomatic aortic stenosis not fulfilling PARTNER study inclusion criteria. Catheter Cardiovasc Interv. Nov 15 2015; 86(6): 1097-104. PMID 26032437
51. Arora S, Strassle PD, Ramm CJ, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Lower Surgical Risk Scores: A Systematic Review and Meta-Analysis of Early Outcomes. Heart Lung Circ. Aug 2017; 26(8): 840-845. PMID 28169084
52. Arora S, Vaidya SR, Strassle PD, et al. Meta-analysis of transfemoral TAVR versus surgical aortic valve replacement. Catheter Cardiovasc Interv. Mar 01 2018; 91(4): 806-812. PMID 29068166
53. Garg A, Rao SV, Visveswaran G, et al. Transcatheter Aortic Valve Replacement Versus Surgical Valve Replacement in Low-Intermediate Surgical Risk Patients: A Systematic Review and Meta-Analysis. J Invasive Cardiol. Jun 2017; 29(6): 209-216. PMID 28570236
54. Singh K, Carson K, Rashid MK, et al. Transcatheter Aortic Valve Implantation in Intermediate Surgical Risk Patients With Severe Aortic Stenosis: A Systematic Review and Meta-Analysis. Heart Lung Circ. Feb 2018; 27(2): 227-234. PMID 28473216
55. Ando T, Takagi H, Grines CL. Transfemoral, transapical and transcatheter aortic valve implantation and surgical aortic valve replacement: a meta-analysis of direct and adjusted indirect comparisons of early and mid-term deaths. Interact Cardiovasc Thorac Surg. Sep 01 2017; 25(3): 484-492. PMID 28549125
56. Gozdek M, Raffa GM, Suwalski P, et al. Comparative performance of transcatheter aortic valve-in-valve implantation versus conventional surgical redo aortic valve replacement in patients with degenerated aortic valve bioprostheses: systematic review and meta-analysis. Eur J Cardiothorac Surg. Mar 01 2018; 53(3): 495-504. PMID 29029105
57. Khan SU, Lone AN, Saleem MA, et al. Transcatheter vs surgical aortic-valve replacement in low- to intermediate-surgical-risk candidates: A meta-analysis and systematic review. Clin Cardiol. Nov 2017; 40(11): 974-981. PMID 29168984
58. Tam DY, Vo TX, Wijeysundera HC, et al. Transcatheter vs Surgical Aortic Valve Replacement for Aortic Stenosis in Low-Intermediate Risk Patients: A Meta-analysis. Can J Cardiol. Sep 2017; 33(9): 1171-1179. PMID 28843328
59. Witberg G, Lador A, Yahav D, et al. Transcatheter versus surgical aortic valve replacement in patients at low surgical risk: A meta-analysis of randomized trials and propensity score matched observational studies. Catheter Cardiovasc Interv. Aug 01 2018; 92(2): 408-416. PMID 29388308
60. Ueshima D, Fovino LN, D'Amico G, et al. Transcatheter versus surgical aortic valve replacement in low- and intermediate-risk patients: an updated systematic review and meta-analysis. Cardiovasc Interv Ther. Jul 2019; 34(3): 216-225. PMID 30232711
61. Levett JY, Windle SB, Filion KB, et al. Meta-Analysis of Transcatheter Versus Surgical Aortic Valve Replacement in Low Surgical Risk Patients. Am J Cardiol. Apr 15 2020; 125(8): 1230-1238. PMID 32089249
62. Vipparthy SC, Ravi V, Avula S, et al. Meta-Analysis of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Patients With Low Surgical Risk. Am J Cardiol. Feb 01 2020; 125(3): 459-468. PMID 31784051
63. Anantha-Narayanan M, Kandasamy VV, Reddy YN, et al. Low-Risk Transcatheter Versus Surgical Aortic Valve Replacement - An Updated Meta-Analysis of Randomized Controlled Trials. Cardiovasc Revasc Med. Apr 2020; 21(4): 441-452. PMID 31678116
64. Kundu A, Sardar P, Malhotra R, et al. Cardiovascular Outcomes with Transcatheter vs. Surgical Aortic Valve Replacement in Low-Risk Patients: An Updated Meta-Analysis of Randomized Controlled Trials. Cardiovasc Revasc Med. Apr 2020; 21(4): 453-460. PMID 31669113
65. Kolkailah AA, Doukky R, Pelletier MP, et al. Cochrane corner: transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis in people with low surgical risk. Heart. Jul 2020; 106(14): 1043-1045. PMID 32482670
66. Zhou Y, Wang Y, Wu Y, et al. Transcatheter versus surgical aortic valve replacement in low to intermediate risk patients: A meta-analysis of randomized and observational studies. Int J Cardiol. Feb 01 2017; 228: 723-728. PMID 27886617

67. Thyregod HG, Steinbruchel DA, Ihlemann N, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. J Am Coll Cardiol. May 26 2015; 65(20): 2184-94. PMID 25787196
68. Nielsen HH, Klaaborg KE, Nissen H, et al. A prospective, randomised trial of transapical transcatheter aortic valve implantation vs. surgical aortic valve replacement in operable elderly patients with aortic stenosis: the STACCATO trial. EuroIntervention. Jul 20 2012; 8(3): 383-9. PMID 22581299
69. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med. Apr 28 2016; 374(17): 1609-20. PMID 27040324
70. Kondur A, Briasoulis A, Palla M, et al. Meta-Analysis of Transcatheter Aortic Valve Replacement Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis. Am J Cardiol. Jan 15 2016; 117(2): 252-7. PMID 26639040
71. Tamburino C, Barbanti M, D'Errigo P, et al. 1-Year Outcomes After Transfemoral Transcatheter or Surgical Aortic Valve Replacement: Results From the Italian OBSERVANT Study. J Am Coll Cardiol. Aug 18 2015; 66(7): 804-812. PMID 26271063
72. Siemieniuk RA, Agoritsas T, Manja V, et al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. BMJ. Sep 28 2016; 354: i5130. PMID 27683246
73. Sondergaard L, Steinbruchel DA, Ihlemann N, et al. Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement: The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial. Circ Cardiovasc Interv. Jun 2016; 9(6). PMID 27296202
74. Thyregod HGH, Ihlemann N, Jorgensen TH, et al. Five-Year Clinical and Echocardiographic Outcomes from the Nordic Aortic Valve Intervention (NOTION) Randomized Clinical Trial in Lower Surgical Risk Patients. Circulation. Feb 01 2019. PMID 30704298
75. Sondergaard L, Ihlemann N, Capodanno D, et al. Durability of Transcatheter and Surgical Bioprosthetic Aortic Valves in Patients at Lower Surgical Risk. J Am Coll Cardiol. Feb 12 2019; 73(5): 546-553. PMID 30732707
76. Reardon MJ, Kleiman NS, Adams DH, et al. Outcomes in the Randomized CoreValve US Pivotal High Risk Trial in Patients With a Society of Thoracic Surgeons Risk Score of 7% or Less. JAMA Cardiol. Nov 01 2016; 1(8): 945-949. PMID 27541162
77. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med. Apr 06 2017; 376(14): 1321-1331. PMID 28304219
78. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. May 02 2019; 380(18): 1706-1715. PMID 30883053
79. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. May 02 2019; 380(18): 1695-1705. PMID 30883058
80. Jorgensen TH, Thyregod HGH, Ihlemann N, et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. Eur Heart J. Aug 07 2021; 42(30): 2912-2919. PMID 34179981
81. Makkar RR, Thourani VH, Mack MJ, et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med. Feb 27 2020; 382(9): 799-809. PMID 31995682
82. Pibarot P, Salaun E, Dahou A, et al. Echocardiographic Results of Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients: The PARTNER 3 Trial. Circulation. May 12 2020; 141(19): 1527-1537. PMID 32272848
83. Shahim B, Malaisrie SC, George I, et al. Postoperative Atrial Fibrillation or Flutter Following Transcatheter or Surgical Aortic Valve Replacement: PARTNER 3 Trial. JACC Cardiovasc Interv. Jul 26 2021; 14(14): 1565-1574. PMID 34294398
84. Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk. J Am Coll Cardiol. Mar 09 2021; 77(9): 1149-1161. PMID 33663731

85. Saleem S, Ullah W, Syed MA, et al. Meta-analysis comparing valve-in-valve TAVR and redo-SAVR in patients with degenerated bioprosthetic aortic valve. Catheter Cardiovasc Interv. Nov 01 2021; 98(5): 940-947. PMID 34110684
86. National Institute For Health And Care Excellence. Interventional procedure overview of valve-in-valve TAVI for aortic bioprosthetic valve dysfunction (IP 1013/2 [IPG653]). June 2019. https://www.nice.org.uk/guidance/ipg653/evidence/overview-final-pdf-6834685357. Accessed December 27, 2021.
87. Phan K, Zhao DF, Wang N, et al. Transcatheter valve-in-valve implantation versus reoperative conventional aortic valve replacement: a systematic review. J Thorac Dis. Jan 2016; 8(1): E83-93. PMID 26904259
88. Chen HL, Liu K. Clinical outcomes for transcatheter valve-in-valve in treating surgical bioprosthetic dysfunction: A meta-analysis. Int J Cardiol. Jun 01 2016; 212: 138-41. PMID 27038719
89. Tam DY, Vo TX, Wijeysundera HC, et al. Transcatheter valve-in-valve versus redo surgical aortic valve replacement for the treatment of degenerated bioprosthetic aortic valve: A systematic review and meta-analysis. Catheter Cardiovasc Interv. Dec 01 2018; 92(7): 1404-1411. PMID 30024102
90. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Jun 10 2014; 63(22): 2438-88. PMID 24603192
91. Nishimura RA, O'Gara PT, Bonow RO. Guidelines Update on Indications for Transcatheter Aortic Valve Replacement. JAMA Cardiol. Sep 01 2017; 2(9): 1036-1037. PMID 28768333
92. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. Feb 02 2021; 77(4): e25-e197. PMID 33342586
93. National Institute For Health And Care Excellence.Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction, Interventional procedures guidance [IPG653]. June 2019. https://www.nice.org.uk/guidance/ipg653. Accessed December 28, 2021.
94. National Institute For Health And Care Excellence. Heart valve disease presenting in adults: investigation and management [NG208]. November 2021. https://www.nice.org.uk/guidance/ng208/chapter/Recommendations#interventions. Accessed December 29, 2021.
95. Centers for Medicaid and Medicare Services. Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R). https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293&bc=ACAAAAAAQAAA&. Accessed December 28, 2021.