MEDICAL POLICY

POLICY TITLE	TRANSCATHETER AORTIC VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

Original Issue Date (Created):	**11/1/2012**
Most Recent Review Date (Revised):	**4/30/2018**
Effective Date:	**11/1/2018**

I. POLICY

Transcatheter aortic valve replacement, with an U.S. Food and Drug Administration FDA-approved transcatheter heart valve system, performed via an approach consistent with the specific device's FDA-approved labeling, may be considered **medically necessary** for patients with aortic stenosis when **all** of the following conditions are present:

- Severe aortic stenosis (see policy guidelines) with a calcified aortic annulus; AND
- NYHA (New York Heart Association) 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 or intermediate risk for open surgery (see Policy Guidelines)

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 (see Policy Guidelines section).

Transcatheter aortic valve replacement is considered **investigational** for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

POLICY GUIDELINES

POLICY TITLE	TRANSCATHETER AORTIC VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

The U.S. Food and Drug Administration (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 high risk for open surgery:

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

The FDA definition of intermediate risk is:

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

For 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 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

Cross-reference:
MP-1.139 Transcatheter Pulmonary Valve Implantation

II. PRODUCT VARIATIONS

TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.132 Transcatheter aortic-valve Implantation for Aortic Stenosis. The FEP Medical Policy manual can be found at*:* *https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies*.

III. DESCRIPTION/BACKGROUND

TOP

Aortic Stenosis
Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries.[1] Congenital abnormalities of the aortic valve,

most commonly a bicuspid valve, increase the risk for aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia.[1] Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis, i.e., 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.

Disease Burden

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,[1] increasing up to 8% of people by age 85 years.[2] 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%.[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 reaches the severe stage, 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 periods of up to 20 years.[4] However, these benefits are accompanied by a 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 (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.

Treatment

Transcatheter aortic valve implantation 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.

Regulatory Status

Two manufacturers have transcatheter aortic valve devices with Food and Drug Administration (FDA) approval. Regulatory status data for these devices are listed in Table 1

Table 1. FDA-Approved Transcatheter Aortic Valve Device Systems

Device and Indication	Manufacturer	Date Cleared	PMA
Edwards SAPIEN Transcatheter Heart Valve System™ • Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach)	Edwards Lifesciences	11/11	P100041
• Expanded to include high-risk aortic stenosis (transapical approach)		10/12	
• Expanded to include replacement of bioprosthetic valve in high risk for death or severe complications of repeat surgery		06/17	
• Expanded to include severe aortic stenosis with intermediate surgical risk		08/16	
Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories • Severe native aortic valve stenosis at high or greater risk for open surgical therapy		07/14	P130009
• Expanded to include failure of bioprosthetic valve in high or greater risk for open surgical therapy		10/15	P130009/S034
• Expanded to include severe aortic stenosis with intermediate surgical risk		08/16	
Medtronic CoreValve System™ • Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy	Medtronic CoreValve	01/14	P130021
• Expanded to include high risk for open surgical therapy		06/16	P130021/S002
• Expanded to include intermediate risk for open surgical therapy		07/17	P130021/S033
Medtronic CoreValve Evolut R System™ • Design iteration for valve and accessories		06/15	P130021/S014
• Expanded to include intermediate risk for open surgical therapy		07/17	P130021/S033
Medtronic CoreValve Evolut PRO System™ • Design iteration for valve and accessories		03/17	P130021/S029
• Expanded to include intermediate risk for open surgical therapy		07/17	P130021/S033

FDA: Food and Drug Administration: PMA: postmarket approval.

Other transcatheter aortic valve systems are under development. The following repositionable valves are under investigation:

- Lotus™ Aortic Valve Replacement System (Boston Scientific)
- Portico™ Transcatheter Aortic Valve (St. Jude Medical)
- JenaValve™ (JenaValve Technology); designed for transapical placement

Several embolic protection devices, which are designed to collect embolic debris distal to the transcatheter aortic valve implantation apparatus and to prevent ischemic stroke, are under

investigation. No devices have FDA approval for use in the United States. Examples include the TriGuard (Keystone Heart) and the Sentinel Cerebral Protection System (Claret Medical).

IV. RATIONALE

TOP

Summary of Evidence

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

For individuals who have severe symptomatic aortic stenosis who are at high risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals at high risk for surgery, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. For patients who are high risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI vs 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 one device over another in all patients. Two

sex-specific studies were also identified in a literature search with the objective of observing mortality rates in women undergoing TAVI or SAVR. Results were varied, and further study is needed. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at intermediate risk for open surgery who receive TAVI, the evidence includes 3 RCTs comparing TAVI with surgical repair including individuals at intermediate surgical risk, 2 RCTs only in patients with intermediate risk, and multiple systematic reviews and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Five RCTs have evaluated TAVI in patients with intermediate risk for open surgery. Three of them, which included over 4000 patients combined, reported noninferiority of TAVI vs SAVR for their composite outcome measures (generally including death and stroke). A subset analysis of patients (n=383) with low and intermediate surgical risk from a fourth trial reported higher rates of death at 2 years for TAVI vs SAVR. The final study (N=70) had an unclear hypothesis and reported 30-day mortality rates favoring SAVR (15% vs 2%, p=0.07) but used a transthoracic approach. The rates of adverse events differed between groups, with bleeding, cardiogenic shock, and acute kidney injury higher in patients randomized to open surgery and permanent pacemaker requirement higher in patients randomized to TAVI. Subgroup analyses of meta-analyses and the transthoracic arm of the Leon et al RCT has suggested that the benefit of TAVI may be limited to patients who are candidates for transfemoral access. Although several RCTs have 2 years of follow-up postprocedure, it is uncertain how many individuals require reoperation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at low risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals selected without specific surgical risk criteria but including patients at low surgical risk, systematic reviews, and nonrandomized cohort studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Limited data are available comparing SAVR with TAVI in patients who had severe aortic stenosis with low risk for open surgery. A systematic review including the low surgical risk patients of these 2 RCTs, and 4 observational studies, with propensity score matching, reported that the 30-day and in-hospital mortality rates were similar for TAVI (2.2%) and SAVR (2.6%). However, TAVI was associated with increased risk of mortality with longer follow-up (median, 2 years; 17.2% vs 12.7%). TAVI was associated with reduced risk for bleeding, renal failure and, an increase in vascular complications and pacemaker implantation compared with SAVR. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

V. DEFINITIONS

TOP

N/A

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are

Covered when medically necessary:

CPT Codes ®							
33361	33362	33363	33364	33365	33366	33367	33368

33369							

**Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved.*

ICD-10-CM Diagnosis Codes	Description
I06.0	Rheumatic aortic stenosis
I06.1	Rheumatic aortic insufficiency
I06.2	Rheumatic aortic stenosis with insufficiency
I06.8	Other rheumatic aortic valve diseases
I06.9	Rheumatic aortic valve disease, unspecified
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.2	Rheumatic disorders of both aortic and tricuspid valves
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves
I08.8	Other rheumatic multiple valve diseases
I08.9	Rheumatic multiple valve disease, unspecified
I35.0	Nonrheumatic aortic (valve) stenosis
I35.1	Nonrheumatic aortic (valve) insufficiency
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency
I35.8	Other nonrheumatic aortic valve disorders
I35.9	Nonrheumatic aortic valve disorder, unspecified
Q23.0	Congenital stenosis of aortic valve
T82.01XA	Breakdown (mechanical) of heart valve prosthesis, initial encounter
T82.01XD	Breakdown (mechanical) of heart valve prosthesis, subsequent encounter
T82.01XS	Breakdown (mechanical) of heart valve prosthesis, sequela
T82.857A	Stenosis of other cardiac prosthetic devices, implants and grafts, initial encounter
T82.857D	Stenosis of other cardiac prosthetic devices, implants and grafts, subsequent encounter
T82.857S	Stenosis of other cardiac prosthetic devices, implants and grafts, sequela

IX. REFERENCES

Top

Abdel-Wahab M, Mehilli J, Frerker C, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. JAMA. Apr 16 2014;311(15):1503-1514. PMID 24682026

Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med. May 8 2014;370(19):1790-1798. PMID 24678937

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 1 2017;25(3):484-492. PMID 28549125

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

Arora S, Vaidya SR, Strassle PD, et al. Meta-analysis of transfemoral TAVR versus surgical aortic valve replacement. Catheter Cardiovasc Interv. Oct 25 2017. PMID 29068166

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

Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. Sep 21 2017;38(36):2739-2791. PMID 28886619

Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.132, Transcatheter Aortic Valve Implantation for Aortic Stenosis. 4/12/18.

Boerlage-Van Dijk K, Kooiman KM, Yong ZY, et al. Predictors and permanency of cardiac conduction disorders and necessity of pacing after transcatheter aortic valve implantation. Pacing Clin Electrophysiol. Nov 2014;37(11):1520-1529. PMID 25040838

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 1 2006;114(5):e84-231. PMID 16880336

Center for Medicare & Medicaid Services. Decision Memo for transcatheter aortic valve replacement (TAVR) (CAG-00430N). 2012; Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430N). Accessed April 30, 2018.

Coeytaux RR, Williams JW, Jr., Gray RN, et al. Percutaneous heart valve replacement for aortic stenosis: state of the evidence. Ann Intern Med. Sep 7 2010;153(5):314-324. PMID 20679543

Conte JV, Hermiller J, Jr., 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

Czerwinska-Jelonkiewicz K, Michalowska I, Witkowski A, et al. Vascular complications after transcatheter aortic valve implantation (TAVI): risk and long-term results. J Thromb Thrombolysis. May 2014;37(4):490-498. PMID 24132402

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 7 2016;67(22):2565-2574. PMID 27050187

Dvir D, Webb JG, Bleiziffer S, et al. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA. Jul 2014;312(2):162-170. PMID 25005653

Fanning JP, Wesley AJ, Walters DL, et al. Neurological injury in intermediate-risk transcatheter aortic valve implantation. J Am Heart Assoc. Nov 15 2016;5(11). PMID 27849158

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):265-276. PMID 21165626

Freeman RV, Otto CM. Spectrum of calcific aortic valve disease: pathogenesis, disease progression, and treatment strategies. Circulation. Jun 21 2005;111(24):3316-3326. PMID 15967862

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

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):1100-1109. PMID 24291283

Genereux P, Kodali SK, Green P, et al. Incidence and effect of acute kidney injury after transcatheter aortic valve replacement using the new valve academic research consortium criteria. Am J Cardiol. Jan 1 2013;111(1):100-105. PMID 23040657

Gensas CS, Caixeta A, Siqueira D, et al. Predictors of permanent pacemaker requirement after transcatheter aortic valve implantation: insights from a Brazilian registry. Int J Cardiol. Aug 1 2014;175(2):248-252. PMID 24880480

Giordana F, D'Ascenzo F, Nijhoff F, et al. Meta-analysis of predictors of all-cause mortality after transcatheter aortic valve implantation. Am J Cardiol. Nov 1 2014;114(9):1447-1455. PMID 25217456

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 1 2018;53(3):495-504. PMID 29029105

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):2714-2720. PMID 16141261

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):1483-1492. PMID 25205802

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

Khatri PJ, Webb JG, Rodes-Cabau J, et al. Adverse effects associated with transcatheter aortic valve implantation: a meta-analysis of contemporary studies. Ann Intern Med. Jan 1 2013;158(1):35-46. PMID 23277899

Khawaja MZ, Thomas M, Joshi A, et al. The effects of VARC-defined acute kidney injury after transcatheter aortic valve implantation (TAVI) using the Edwards bioprosthesis. EuroIntervention. Sep 2012;8(5):563-570. PMID 22995082

Kim WJ, Ko YG, Han S, et al. Predictors of permanent pacemaker insertion following transcatheter aortic valve replacement with the CoreValve revalving system based on

computed tomography analysis: an Asian multicenter registry study. J Invasive Cardiol. Jul 2015;27(7):334-340. PMID 26136283

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):252-257. PMID 26639040

Latib A, Ielasi A, Montorfano M, et al. Transcatheter valve-in-valve implantation with the Edwards SAPIEN in patients with bioprosthetic heart valve failure: the Milan experience. EuroIntervention. Mar 2012;7(11):1275-1284. PMID 22278193

Lenders GD, Collas V, Hernandez JM, et al. Depth of valve implantation, conduction disturbances and pacemaker implantation with CoreValve and CoreValve Accutrak system for Transcatheter Aortic Valve Implantation, a multi-center study. Int J Cardiol. Oct 20 2014;176(3):771-775. PMID 25147076

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):1597-1607. PMID 20961243

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):1609-1620. PMID 27040324

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):1522-1528. PMID 7594080

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):1220-1225. PMID 8459080

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 7 2014;35(38):2672-2684. PMID 24682842

Linke A, Woitek F, Merx MW, et al. Valve-in-valve implantation of Medtronic CoreValve prosthesis in patients with failing bioprosthetic aortic valves. Circ Cardiovasc Interv. Oct 1 2012;5(5):689-697. PMID 23048050

Mack MJ, Brennan JM, Brindis R, et al. Outcomes following transcatheter aortic valve replacement in the United States. JAMA. Nov 20 2013;310(19):2069-2077. PMID 24240934

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):2477-2484. PMID 25788234

Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. N Engl J Med. May 3 2012;366(18):1696-1704. PMID 22443478

Meredith IT, Walton A, Walters DL, et al. Mid-term outcomes in patients following transcatheter aortic valve implantation in the CoreValve Australia and New Zealand Study. Heart Lung Circ. Mar 2015;24(3):281-290. PMID 25456213

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):1443-1447. PMID 25784513

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):90-95. PMID 25320140

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):383-389. PMID 22581299

Nishimura RA, O'Gara PT, Bonow RO. Guidelines update on indications for transcatheter aortic valve replacement. JAMA Cardiol. Sep 1 2017;2(9):1036-1037. PMID 28768333

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):2438-2488. PMID 24603192

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

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):850-860. PMID 23756547

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 1 2018;250:66-72. PMID 29169764

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):242-249. PMID 19110790

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):1972-1981. PMID 24657695

Raval J, Nagaraja V, Eslick GD, et al. Transcatheter valve-in-valve implantation: a systematic review of literature. Heart Lung Circ. Nov 2014;23(11):1020-1028. PMID 25038030

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):2869-2876 e2861-2867. PMID 25152474

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):113-121. PMID 26055947

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 1 2016;1(8):945-949. PMID 27541162

Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. Apr 6 2017;376(14):1321-1331. PMID 28304219

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 1 2011;124(18):1964-1972. PMID 21969017

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 7 2012;60(6):548-558. PMID 22818074

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):1080-1090. PMID 20096533

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):1097-1104. PMID 26032437

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

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

Siontis GC, Juni P, Pilgrim T, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. J Am Coll Cardiol. Jul 15 2014;64(2):129-140. PMID 25011716

Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. Jun 9 2011;364(23):2187-2198. PMID 21639811

Søndergaard 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

Subban V, Savage M, Crowhurst J, et al. Transcatheter valve-in-valve replacement of degenerated bioprosthetic aortic valves: a single Australian Centre experience. Cardiovasc Revasc Med. Nov-Dec 2014;15(8):388-392. PMID 25456416

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):158-168. PMID 25011720

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):513-519. PMID 23816417

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

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

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

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):2184-2194. PMID 25787196

Toggweiler S, Wood DA, Rodes-Cabau J, et al. Transcatheter valve-in-valve implantation for failed balloon-expandable transcatheter aortic valves. JACC Cardiovasc Interv. May 2012;5(5):571-577. PMID 22625197

Van Mieghem NM, Tchetche D, Chieffo A, et al. Incidence, predictors, and implications of access site complications with transfemoral transcatheter aortic valve implantation. Am J Cardiol. Nov 1 2012;110(9):1361-1367. PMID 22819428

Villablanca P, Briceño D, Makkiya M, et al. Long-term outcomes of transcatheter versus surgical aortic valve replacement for severe aortic stenosis: a meta-analysis and meta-regression: PROSPERO 2016:CRD42016036772. PROSPERO International prospective register of systematic reviews 2016; https://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42016036772. Accessed April 30, 2018.

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

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):1797-1806. PMID 26718510

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. Feb 1 2018. PMID 29388308

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):1327-1334. PMID 26383718

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

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. Nov 12 2016;228:723-728. PMID 27886617

Zorn GL, 3rd, 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):1014-1022, 1023 e1011-1013. PMID 26614412

IX. POLICY HISTORY

TOP

MP-1.135	**CAC 6/26/12** New policy- Adopt BCBSA -Transcatheter aortic valve replacement, performed via the transfemoral approach, is considered medically necessary for patients with aortic stenosis when specific criteria have been met. **8/13/12** Medicare variation added.
	12/26/2012 New codes added
	CAC 7/30/13 Minor revision, 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. References updated. Guidelines added. FEP variation added. Policy coded.
	12/19/2013- New 2014 Code updates made.
	CAC 3/24/15 Minor revision. Policy revised to remove statement that "procedures performed via the transaxillary, transiliac, transaortic, or other approaches" are investigational, to reflect that the approval of the CoreValve device that is labeled for use via transaxillary, transfemoral, and transaortic approaches. A statement was added that devices should be used according to their FDA approved indication. References, guidelines, background and rationale updated. Codes reviewed.
	CAC 5/31/16 Consensus. No change to policy statements. References and rationale reviewed**.** Coding reviewed**.**
	Admin update 1/1/17: Product variation section reformatted.
	CAC 11/29/16 Minor revision. Medically necessary statement added for valve-in-valve implantation in patients at high or prohibitive risk for open surgery. Background, rationale, and references updated. Coding reviewed.
	12/19/17 Consensus review. No changes to the policy statements. Rationale and references updated.
	4/30/18 Minor review. Policy statements changed to add patients with aortic stenosis at intermediate surgical risk to first medically necessary statement. References and background updated. Rationale condensed. Coding updated.

POLICY TITLE	TRANSCATHETER AORTIC VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

Top