# MEDICAL POLICY

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

| CLINICAL BENEFIT | ☐ MINIMIZE SAFETY RISK OR CONCERN.<br>☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.<br>☐ ASSURE APPROPRIATE LEVEL OF CARE.<br>☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.<br>☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.<br>☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
|---|---|
| **Effective Date:** | **11/1/2024** |



## 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 device's FDA approved labeling, may be considered **medically necessary** for individuals with native valve aortic stenosis when **ALL** of the following conditions are present:

- Severe aortic stenosis (see Policy Guidelines section) with a calcified aortic annulus; **AND**
- New York Heart Association heart failure Class II, III, or IV symptoms; **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 **medically necessary** when **ALL** of the following conditions are present:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; **AND**
- New York Heart Association heart failure class II, III or IV symptoms; **AND**
- Individual is not an operable candidate, or is at increased risk for open surgery, as assessed by two cardiovascular specialists (including a cardiac surgeon).

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

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

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**POLICY GUIDELINES**

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 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 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 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

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

**FEP PPO** Refer to FEP Medical Policy Manual. 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

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**Aortic Stenosis**

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Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries. Congenital abnormalities of the aortic valve, most commonly a bicuspid or unicuspid valve, increase the risk for aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia. Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis (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 replacement of the diseased valve with a bioprosthetic or mechanical valve.

### 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, increasing up to 8% of people by age 85 years. 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%. In the United States, more than 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

Aortic stenosis does not cause substantial morbidity or mortality when the disease is mild or moderate in severity. By the time it becomes severe, there is an untreated mortality rate of approximately 50% within 2 years. Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for periods of up to 20 years. However, these benefits are accompanied by a perioperative mortality of approximately 3% to 4% and substantial morbidity, both of which increase with advancing age.

### Unmet Needs

Many patients with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of patients presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities. For patients who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes. Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction, 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 who are at increased risk for open surgery.

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### 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 (transcatheter aortic valve implantation) 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. 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). 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.

### Regulatory Status

Multiple 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™<br>• Severe native aortic valve stenosis determined to be inoperable for open aortic valve replacement (transfemoral approach) | Edwards Lifesciences | 11/11 | P100041 |
| • Edwards SAPIEN™ Transcatheter Heart Valve, Model 9000TFX | | 10/12 | P110021 |

| | | | |
|---|---|---|---|
| • Expanded to include high-risk aortic stenosis (transapical approach) | | | |
| • Edwards SAPIEN XT Transcatheter Heart Valve (model 9300TFX) and accessories<br>• Severe native aortic valve stenosis at high or greater risk for open surgical therapy | | 7/14 | 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 | | 8/16 | P130009/S057 |
| • SAPIEN 3 THV System, a design iteration<br>• Severe aortic stenosis with high or greater risk for open surgical therapy | | 06/15 | P140031 |
| • Expanded to include failure of a bioprosthetic valve with high or greater risk for open surgical therapy | | 06/17 | P140031/S028 |
| • SAPIEN 3 Ultra THV System, a design iteration<br><br>Note: In August 2019, FDA issued a recall for the Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System (Recall event ID: 83293) due to "reports of burst balloons which have resulted in significant difficulty retrieving the device into the sheath and withdrawing the system from the patient during procedures". | | 12/18 | P140031 |
| • Expanded to include severe aortic stenosis with low surgical risk | | 08/19 | P140031/S085 |
| • Expanded to include failure of a biroprosthetic valve with high or greater risk for open surgical therapy | | 09/20 | P140031/S112 |
| Medtronic CoreValve System™<br>• 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, includes porcine pericardial tissue wrap) | | 03/17 | P130021/S029 |
| • Expanded to include intermediate risk for open surgical therapy | | 07/17 | P130021/S033 |
| • Expanded to include severe aortic stenosis with low surgical risk | | 08/19 | P130021/S058 |
| • Medtronic CoreValve Evolut PRO+ System™ (design iteration) | | 08/19 | P130021/S059 |
| • Medtronic Evolut™ FX System (design iteration) | | 8/21 | P130221/S091 |
| LOTUS Edge™ Valve System<br>• Severe native aortic stenosis at high or greater risk for open surgical therapy<br>• **See note** | Boston Scientific Corporation | 04/19 | P180029 |
| Portico™ with FlexNav™<br>• Severe native aortic stenosis at high or greater risk for open surgical therapy | Abbott Medical | 9/21 | P190023 |
| Navitor™ Transcatheter Aortic Valve Implantation System with FlexNav<br>• Severe native aortic stenosis at high risk or greater risk for open surgical therapy | Abbott Medical | 10/23 | P190023/S016 |

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

**NOTE**: in January 2021, Boston Scientific Corporation announced a global, voluntary recall of all unused inventory of the LOTUS Edge™ Valve System due to complexities associated with the product delivery system. There are no safety concerns for patents who have the LOTUS Edge™ Valve System currently implanted. Boston Scientific has chosen to retire the entire LOTUS product platform immediately rather than develop and reintroduce an enhanced delivery system. All related commercial, clinical, research and development, and manufacturing activities will cease.

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

- JenaValve™ (JenaValve Technology); designed for transapical placement.

In June 2017, the Sentinel® Cerebral Protection System (Boston Scientific; previously Claret Medical, Inc.) was granted a de novo classification by the FDA (DEN160043; class II; product code: PUM).8, The Sentinel system is a temporary catheter indicated for use as an embolic protection deice to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 mm to 15 mm for the brachiocephalic and 6.5 mm to 10 mm in the left common carotid. The new classification applies to this device and substantially equivalent devices of this generic type.

On August 3, 2021, the FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee met to discuss and make recommendations on the 510(k) submission for the TriGUARD 3™ Cerebral Embolic Protection Device (Keystone Heart).9, With the Sentinel system serving as the predicate device, the panel expressed that the proposed indications for use of the TriGUARD 3 device were not supported by the safety and effectiveness data from the REFLECT II trial. Previously, the TriGUARD 3 device was granted Conformité Européene (CE) mark approval in Europe in March 2020.

## IV. RATIONALE

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### 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 a randomized controlled trial (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 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 a meaningful improvement in the net health outcome.

For individuals who have severe symptomatic aortic stenosis who are at high-risk for open surgery who receive TAVI, the evidence includes 2 RCTs comparing TAVI with surgical repair in individuals at high-risk for surgery and 1 RCT comparing 2 types of valves, multiple nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and

morbidity. For patients who are high-risk for open surgery and are surgical candidates, the PARTNER A trial reported noninferiority for survival at 1 year for the balloon-expandable valve compared with open surgery. In this trial, TAVI patients also had higher risks for stroke and vascular complications. Nonrandomized comparative studies of TAVI versus open surgery in high-risk patients have reported no major differences in rates of mortality or stroke between the 2 procedures. Since 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 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 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 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 versus surgical aortic valve replacement (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 post-procedure, 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 overall survival, 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. 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” 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 overall survival, 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 events. 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.

**Additional Information**
**2024 Input**
Clinical input was sought to help determine whether the use of transcatheter aortic valve-in-valve (ViV) implantation for individuals who have valve dysfunction and aortic stenosis or

regurgitation after open surgical aortic valve repair provides a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 4 respondents, including: 3 physician-level responses with academic affiliations identified by specialty medical societies and 1 physician-level response identified by an academic health system.

For individuals with valve dysfunction and aortic stenosis or regurgitation after open surgical aortic valve repair, clinical input provides consistent support that the use of transcatheter ViV implantation provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice.
The following patient selection criteria for transcatheter aortic valve replacement (TAVR) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (ViV) were informed by clinical input and the published evidence:

- Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
- New York Heart Association heart failure class II, III, or IV symptoms; AND
- Individual is not an operable candidate for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon); OR
- Individual is an operable candidate but is considered at increased surgical risk for open surgery, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon; see Policy Guidelines section); OR
- Individual is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies AND/OR has a complex intrathoracic surgical history, as documented by at least 2 cardiovascular specialists (including a cardiac surgeon).

Respondents noted that there are certain technical impediments that may increase the risk of redo surgical aortic valve replacement (rSAVR) that are not captured by Society of Thoracic Surgeons risk score, including porcelain aorta, prior mediastinal surgeries, patent bypass grafts, or a particularly adherent left internal mammary artery. Additionally, elderly individuals that do not meet high-risk criteria can benefit from the early recovery offered by TAVR. Clinical input also emphasized that there is unlikely to be equipoise for randomization of patients with structural bioprosthetic valve degeneration to aortic valve replacement via any modality versus conservative therapy.

## V. DEFINITIONS

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N/A

## VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are

different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

## VII. DISCLAIMER

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*Capital Blue Cross' 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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

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**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 eligible for separate reimbursement.

**Not Medically Necessary; therefore, not covered:**

| Procedure Codes | | | | | | | |
|---|---|---|---|---|---|---|---|
| 33370 | | | | | | | |

**Covered when medically necessary:**

| Procedure Codes | | | | | | | |
|---|---|---|---|---|---|---|---|
| 33361 | 33362 | 33363 | 33364 | 33365 | 33366 | 33367 | 33368 |
| 33369 | | | | | | | |

| 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

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## X. POLICY HISTORY

TOP

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

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|---|---|
| MP 1.135 | **04/02/2020 Minor Review**. Policy statements changed to specify patient cannot have Unicuspid or Bicuspid aortic valves for TAVI. Coding reviewed. Policy Guideline, Background, Rationale, References updated. |
| | **03/31/2021 Consensus Review.** No change to policy statement or coding. References updated. |
| | **12/01/2021 Administrative update.** New code 33370 added to policy. Effective 1/1/2022 |
| | **03/25/2022 Consensus Review.** No change to policy statement. Product variation and FEP language updated. Background and Rationale revised. References added. |
| | **03/07/2023 Minor Review.** Policy statement changed to add Not Medically Necessary statement for use of cerebral embolic protection devices in individuals undergoing TAVI. References reviewed and updated. Code 33370 moved to Not Medically Necessary. Background and rationale updated. |
| | **05/02/2024 Minor Review.** Removed requirement for EF >20%. Updated statement to include individuals at increased risk for open surgery as candidates for ViV TAVR. Cerebral embolic protection device is now INV from NMN. Rationale and references updated. Updated 33370 to INV from NMN, no other coding changes. |

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