Transcatheter Heart Valve Procedures (for Ohio Only)

Policy Number: CS123OH.B
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Ü Instructions for Use

Table of Contents **Page**

Related Policies
None

Application

This Medical Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

Aortic

For medical necessity clinical coverage criteria for transcatheter aortic valve replacement, refer to the InterQual® CP: Procedures, Transcatheter Aortic Valve Replacement (TAVR).

Click here to view the InterQual® criteria.

Transcatheter valve-in-valve (ViV) replacement within a failed bioprosthetic aortic valve is proven and medically necessary for individuals at high or prohibitive surgical risk [Predicted Risk of Mortality (PROM) score of ≥ 8%] when performed according to FDA labeled indications, contraindications, warnings, and precautions.

Note: Requests for transcatheter aortic heart valve replacement for low-flow/low-gradient aortic stenosis in individuals who do not meet the peak velocity, mean gradient, and valve area criteria listed above will be considered on a case-by-case basis. These requests will be evaluated using recommendations from the American College of Cardiology/American Heart Association Guideline for the Management of Patients With Valvular Heart Disease (Otto et al., 2021) when all the clinical evaluation has been facilitated by a transcatheter aortic heart valve replacement expert and after appropriate additional testing has been conducted.

Mitral

For medical necessity clinical coverage criteria for transcatheter mitral valve repair, refer to the InterQual® CP: Procedures, Transcatheter Mitral Valve Edge-to-Edge Repair (TEER).

Click here to view the InterQual® criteria.

Transcatheter mitral heart valve repair (e.g., annuloplasty), except where noted above, is unproven and not medically necessary due to insufficient evidence of efficacy. Transcatheter mitral heart valve reconstruction or replacement is unproven and not medically necessary due to insufficient evidence of efficacy.

Pulmonary

Transcatheter pulmonary heart valve replacement and related devices (e.g., Alterra) are proven and medically necessary when used according to FDA labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract (RVOT) dysfunction with one of the following clinical indications for intervention:

- Moderate or greater pulmonary regurgitation; and/or
- Pulmonary stenosis with a mean RVOT gradient ≥ 35 mmHg

Tricuspid

Transcatheter tricuspid heart valve repair, reconstruction, or replacement is unproven and not medically necessary due to insufficient evidence of efficacy.

The following transcatheter heart valve devices and/or procedures are unproven and not medically necessary due to insufficient evidence of efficacy:

- Cerebral protection devices (e.g., Sentinel™)
- Valve-in-valve (ViV) replacement within a failed bioprosthesis for mitral, pulmonary, or tricuspid valves
- Transcatheter superior and inferior vena cava prosthetic valve implantation (CAVI) are unproven and not medically necessary due to insufficient evidence of efficacy

Definitions

New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994):

- I - No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
- II - Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
- III - Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- IV - Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Predicted Risk of Mortality (PROM): The Society of Thoracic Surgeons (STS) PROM score is a predictor of 30-day mortality after cardiac procedures (Otto et al., 2020).

Shared Decision-Making (SDM): SDM is a process by which physicians and individuals work together to choose the treatment option that best reflects the clinical evidence and the individual's values and preferences (Coylewright et al., 2020).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

CPT Code	Description
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (e.g., thoracotomy, transapical)
0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)
0646T	Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
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 (e.g., median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., 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 (e.g., 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 (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed
33999	Unlisted procedure, cardiac surgery
93799	Unlisted cardiovascular service or procedure

Description of Services

The four natural valves of the heart (aortic, pulmonary, mitral, and tricuspid) act as one-way valves to direct the flow of blood to the lungs and aorta. Heart valves with congenital defects or those that become diseased over time can result in either a leaky valve (regurgitation/incompetence/insufficiency) or a valve that does not open wide enough (stenosis).

Conventional treatment of structural heart valve disorders is surgical repair or replacement requiring open-heart surgery using cardiopulmonary bypass. Transcatheter (percutaneous or catheter-based) valve procedures use catheter technology to access the heart and manage heart valve disorders without the need for open-heart surgery and cardiopulmonary bypass. During the procedure, a compressed artificial heart valve or other device is attached to a wire frame and guided by a catheter to the heart. Once in position, the wire frame expands, allowing the device to fully open.

Aortic Valve

The aortic valve directs blood flow from the left ventricle into the aorta. Aortic valve stenosis, a common valvular disorder in older adults, is a narrowing or obstruction of the aortic valve that prevents the valve leaflets from opening normally. When the aortic valve does not open properly, the left ventricle has to work harder to pump enough blood through the narrowed opening to the rest of the body. Reduced blood flow can cause chest pain, shortness of breath, excess fluid retention and other symptoms. Left untreated, severe aortic stenosis can lead to left ventricular hypertrophy and heart failure. The various stages of valvular aortic stenosis are addressed by Otto et al. (2020).

The standard for treating severe, symptomatic aortic stenosis is surgical replacement with a prosthetic valve. Transcatheter aortic valve replacement (TAVR) is a minimally invasive alternative to surgical valve replacement. Transcatheter aortic valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Depending on individual anatomy, possible access routes to the aortic valve include transfemoral (percutaneous or endovascular approach), transapical, subaxillary or transaortic approaches. The procedure is done without removing the diseased native valve.

Bicuspid Aortic Valve

Bicuspid aortic valve (BAV) is common, and many patients have left-sided heart obstructive disease of varying severity, from hypoplastic left-sided heart syndrome to minimal aortic stenosis or coarctation of the aorta. Significant enlargement of the thoracic aorta may progress to catastrophic aortic dissection and rupture (Silberbach et al., 2018). The aortic valve separates the left ventricle and the aorta. Flaps of tissue (cusps) on the valve open and close with each heartbeat and make sure blood flows in the right direction. The aortic valve usually has three cusps (tricuspid aortic valve) but sometimes has two cups (bicuspid). On rare occasions, some individuals are born with an aortic valve that has one cusp (unicuspid) or four cusps (quadricuspid) (Mayo Clinic, 2022). Congenital BAV is characterized by the presence of a low ridge or raphe along the aortic aspect of the conjoined cusp. Acquired BAV may result from acquired fibrous tissue fusion of the adjacent halves of two cusps and is characterized by a tall raphe, the upper edge of which corresponds with the upper level of the aortic cusps. In other cases, the ridge is a protrusion of the aorta and not derived from fused cuspid tissue. Such valves are considered to portray a condition which may be termed pseudo-acquired congenital BAV. The acquired BAV in some cases is combined of this congenital process and acquired fusion of cuspid tissue (Waller et al., 1973). A BAV may cause heart problems including 1) aortic valve stenosis, where the valve may not open fully and blood flow from the heart to the body is reduced or blocked; 2) aortic valve regurgitation, where the aortic valve does not close tightly causing blood to flow backward; and 3) aortopathy, when an enlarged aorta increases the risk of aortic dissection. Individuals with BAV are more likely to develop infective endocarditis (Mayo Clinic, 2022).

Mitral Valve

The mitral valve directs blood flow from the left atrium into the left ventricle. Mitral regurgitation (MR) occurs when the mitral valve does not close properly, allowing blood to flow backwards from the ventricle to the atrium. MR is sometimes referred to as mitral incompetence or mitral insufficiency. Primary, or degenerative, MR is usually caused by damage to the valve components (e.g., leaflets, attached chords or adjacent supporting tissue). Secondary, or functional, MR is typically due to changes in the shape of the left ventricle that pull the leaflets apart, preventing complete closure. Left untreated, moderate to severe MR can lead to congestive heart failure. MR that cannot be managed conservatively may require surgical valve repair or replacement.

Transcatheter mitral valve replacement (TMVR) is a minimally invasive alternative to surgical valve replacement. Transcatheter mitral valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Depending on individual anatomy, possible access routes to the mitral valve include transfemoral (percutaneous or endovascular approach), transseptal, transapical or transthoracic approaches. The procedure is done without removing the diseased native valve.

Transcatheter leaflet repair, percutaneous annuloplasty, artificial chordae tendineae and annulus reconstruction are minimally invasive approaches to repair damaged mitral valves. Transcatheter leaflet repair keeps the two valve leaflets more closely fitted together, thereby reducing regurgitation. The procedure, based on the surgical edge-to-edge technique, creates a double orifice using a clip instead of a suture to secure the leaflets. The device consists of a steerable guide catheter, including a clip delivery device and a two-armed, flexible metal clip covered in polyester fabric. A transseptal puncture is required to implant the device in the left side of the heart. Access to the mitral valve is achieved via the femoral vein.

Percutaneous transcatheter annuloplasty attempts to replicate the functional effects of open surgical annuloplasty by reshaping the mitral annulus from within the coronary sinus. The coronary sinus is a large vein located along the heart's outer wall, between the left atrium and left ventricle, adjacent to the mitral valve.

Various artificial chordae tendineae and annulus reconstruction devices are in the early stages of development.

Pulmonary Valve

The pulmonary valve directs blood flow from the right ventricle into the lungs. Disorders of the pulmonary valve are often due to congenital heart disease such as tetralogy of Fallot, pulmonary atresia, transposition of the great arteries and double-outlet right ventricle. Surgery to replace the valve with a bioprosthesis may also include a conduit (graft) to open the RVOT. Over time, the valved conduit may fail, leading to pulmonary valve stenosis (narrowing), pulmonary valve regurgitation (incompetence/insufficiency) or a combination of the two. Because individuals undergoing this procedure are typically children or adolescents, the bioprosthetic valve will require revisions as the individual grows.

Transcatheter pulmonary valve implantation, a minimally invasive alternative to surgical valve repair or replacement, is designed to reduce the number of surgeries needed throughout an individual’s lifetime. Transcatheter pulmonary valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Access to the pulmonary valve is most often achieved via the femoral vein. Depending on the device, the replacement valve can be positioned in a native or surgically-repaired RVOT.

Tricuspid Valve

The tricuspid valve directs blood flow from the right atrium into the right ventricle. Tricuspid regurgitation (TR) occurs when the tricuspid valve does not close properly, allowing blood to flow backwards from the ventricle to the atrium. TR is sometimes referred to as tricuspid incompetence or tricuspid insufficiency. The gold standard for treating tricuspid valve disease is surgical annuloplasty. Devices for transcatheter tricuspid valve repair, reconstruction and replacement are in the early stages of development.

Valve-in-Valve Procedures

Transcatheter heart valve implantation within an existing bioprosthetic valve, also called a valve-in-valve procedure, replaces a previously implanted bioprosthetic heart valve that has failed or degenerated over time.

Cerebral Protection

Transcatheter cerebral embolic protection devices are designed to filter and collect debris released during TAVR procedures. These devices are intended to reduce the risk of stroke and decline in cognitive function following surgery.

Clinical Evidence

Aortic Valve

Using registry data, Ribeiro et al. (2018) evaluated clinical outcomes and changes in LVEF following TAVR in patients with classic low-flow, low-gradient aortic stenosis (LFLG-AS). A total of 287 patients were included in the analysis. Clinical follow-up was obtained at one and 12 months, and yearly thereafter. TAVR was associated with good periprocedural outcomes among patients with LFLG-AS and reduced LVEF. However, approximately one third of patients with LFLG AS who underwent TAVR

had died by two-year follow-up; with pulmonary disease, anemia and residual paravalvular leak associated with worse outcomes. LVEF improved following TAVR, but dobutamine stress echocardiography (DSE) did not predict clinical outcomes or LVEF changes over time. Data from this multicenter registry supports an expanding role for TAVR among patients with LFLG severe AS and reduced LVEF. NCT01835028).

An ECRI Clinical Evidence Assessment was conducted to evaluate SAPIENs safety and effectiveness and how they compare with those of other TAVR devices (including the second-generation SAPIEN XT valve) and SAVR. Review and meta-analysis found no statistical difference in technical success, periprocedural mortality, complications, and regurgitation resolution in patients with bicuspid native aortic valves and treated with SAPIEN 3, SAPIEN XT, CoreValve, Evolut R or Pro, Lotus, Direct Flow, or Venus (ECRI 2022; Quintana et al., 2020).

A systematic review and meta-analysis conducted by Du et al. (2021) aimed to compare procedural and 30-day outcomes after TAVI between type 0 and type 1 BAV. Studies comparing the outcomes of TAVI in Sievers type 0 vs. type 1 BAV were retrieved from PubMed, EMBASE, Cochrane Library, and Web of Science from inception to May 2021. The data were extracted regarding the study characteristics and outcomes. The odds ratios (ORs) with 95% CIs were pooled for procedural and 30-day outcomes. Six observational studies were included with determined type 0 BAV in 226 patients and type 1 BAV in 902 patients. The patients with type 0 BAV were slightly younger, had larger supra-annular structure, and more frequently implanted self-expanding prosthesis compared with type 1 BAV. In the pooled analyses, the patients with type 0 BAV had a similar incidence of procedural death (OR = 2.6, 95% CI 0.7-10.3), device success (OR = 0.6; 95% CI 0.3-1.3), and ≥ mild (OR = 0.8; 95% CI 0.4-1.6) or moderate (OR = 0.9, 95% CI 0.4-1.8) paravalvular leak, whereas higher mean aortic gradient (mean difference = 1.4 mmHg, 95% CI 0.03-2.7) and increased coronary compromise risk (OR = 7.2; 95% CI 1.5-34.9), compared with type 1 BAV. The incidence of death (OR = 1.2; 95% CI 0.5-3.1), stroke (OR = 0.5; 95% CI 0.1-2.4), and new pacemaker (OR = 0.6; 95% CI 0.2-2.2) at 30 days were not different between the BAV morphologies ($p > 0.05$). The treatment effect heterogeneity across the studies for the above outcomes were low. The authors concluded that patients with type 0 BAV appeared to have similar short-term outcomes after TAVI compared with type 1 BAV. In addition, the authors stated TAVI for type 0 BAV aortic stenosis might lead to an elevated coronary obstruction risk and suboptimal aortic valvular hemodynamics. Limitations include selection bias as the trials included were either small feasibility studies or large retrospective registries, with inconsistent inclusion and exclusion criteria. The short-term follow-up did not allow for assessment of intermediate and long-term outcomes. Further investigation is needed before clinical usefulness of this procedure is proven.

An ECRI Clinical Evidence Assessment found inconclusive evidence on the HAART 200 aortic annuloplasty device (BioStable Science & Engineering, Inc.) due to too few or no data on outcomes and comparisons of interest to treat moderate to severe aortic insufficiency in patients with bicuspid aortic valve disease. Study results were at high risk of bias due to small sample size and lack of controls, blinding and randomization. No studies reported on long-term follow-up or comparison of aortic valve repair using HAART 200 with aortic valve replacement (ECRI, 2020).

Quintana et al. (2019) conducted a meta-analysis to assess 1-year mortality after TAVR in patients with bicuspid AS using a literature search from the Cochrane, PubMed, ClinicalTrials, SCOPUS, and EMBASE databases. Short-term outcomes that could potentially impact one-year mortality were analyzed. After evaluating 380 potential articles, 5 observational studies were selected. A total of 3,890 patients treated with TAVR were included: 721 had bicuspid and 3,169 had tricuspid AS. No statistical difference between the baseline characteristics of the two groups of patients was seen outside of mean aortic gradient. The primary endpoint of 1-year all-cause mortality revealed 85 deaths in 719 patients (11.82%) with bicuspid AS compared to 467 deaths in 3,100 patients (15.06%) with tricuspid AS, with no statistically significant difference between both groups [relative risk (RR) 1.03; 95% CI 0.70-1.51]. Bicuspid AS was associated with a decrease in device success (RR 0.62; 95% CI 0.45-0.84) and an increase in moderate-to-severe prosthetic valve regurgitation (RR 1.55; 95% CI 1.07-2.22) after TAVR compared to tricuspid AS. The effect of meta-regression coefficients on 1-year all-cause mortality was not statistically substantial for any patient baseline characteristics. The authors concluded when comparing TAVR procedure in tricuspid AS versus bicuspid AS, there was no difference noted in 1-year all-cause mortality. The small number of patients in each study and the observational nature of studies evaluating 1-year outcomes in patients with bicuspid AS undergoing TAVR are limitations of this meta-analysis.

Kanjanahattakij et al. (2018) conducted a systematic review and meta-analysis to evaluate evidence of TAVR in patients with severe aortic stenosis and BAV stenosis compared with TAV. Using professional databases, the authors searched for relevant articles featuring cohort studies that included patients with BAV and TAV who underwent TAVR studies, of which reported outcomes of interest included mortality and complications in both groups. Pooled effect size was calculated with a random-effect model and weighted for the inverse of variance, to compare outcomes post-TAVR between BAV and TAV. Nine studies

were included in the meta-analysis. There was no statistically significant difference in the 30-day mortality rate in patients with BAV compared with TAV (OR: 1.27, 95% CI: 0.84-1.93, I2 = 0). Patients with BAV were more likely to have a moderate to severe paravalvular leak (9 studies; OR: 1.42, 95% CI: 1.08-1.87, I2 = 0) and conversion to surgery (5 studies; OR: 5.48, 95% CI: 1.74-17.27, I2 = 0), and less likely to have device success compared with patients with TAV (5 studies; OR: 0.57, 95% CI: 0.40-0.81, I2 = 0%). The authors concluded there was no difference in mortality post-TAVR in patients with BAV compared with TAV. The short-term follow-up did not allow for assessment of intermediate and long-term outcomes. Further research with randomized controlled trials is needed to validate these findings.

Pulmonary Valve

A Hayes report concluded that there is insufficient evidence to draw conclusions regarding the effectiveness and safety of percutaneous pulmonary valve implantation (PPVI) using SAPIEN 3 and SAPIEN XT valves for the treatment of right ventricular outflow tract (RVOT). Substantial uncertainty exists regarding the long-term durability and efficacy compared with open heart surgery (Hayes, 2022).

Chatterjee et al. (2017) performed a systematic review and meta-analyses of observational studies evaluating transcatheter pulmonary valve implantation. Nineteen studies (n = 1,044) with five or more patients and at least six months of follow-up were included. Thirteen studies used the Melody valve, three used the Edwards SAPIEN or SAPIEN XT valves and three used both Melody and Edwards valve systems. Procedural success rate was 96.2% with a conduit rupture rate of 4.1% and coronary complication rate of 1.3%. The authors reported favorable updated estimates of procedural and follow-up outcomes after transcatheter pulmonary valve implantation. They also noted that widespread adoption of pre-stenting has improved long-term outcomes in these patients (This systematic review includes Cheatham et al. 2015, Armstrong et al. 2014, Butera et al. 2013 and Eicken et al. 2011 which were previously cited in this policy).

Harmony

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of the Harmony transcatheter pulmonary valve. Further results from comparative studies or randomized controlled trials are needed to determine safety, efficacy and durability of the device.

Benson et al. (2020) reported 3-year clinical and hemodynamic outcomes in a follow-up to the Bergersen et al. (2017) feasibility study. Of the original 20 implanted patients, 17 completed 3-year follow-up. Results showed good valve function in most, and the absence of moderate/severe paravalvular leak and significant late frame fractures. Two patients developed significant neointimal tissue ingrowth requiring ViV treatment, while all others had no clinically significant RVOT obstruction. The authors noted that these results are encouraging, but further follow-up is required. At 5 years, Gillespie et al. (2021) reported in a letter to the editor sustained valve function with freedom from moderate-to-severe valve or perivalvular leak and no reports of endocarditis. Two patients underwent surgical explant. There were 3 catheter-based reinterventions performed in 2 patients who both ultimately underwent Melody ViV procedures. One patient passed away shortly after the 3-year follow-up assessment. These and the original publication described below are limited by lack of a comparison group undergoing a different therapeutic approach.

Bergersen et al. (2017) reported clinical outcomes from an early feasibility study to assess the self-expanding Harmony transcatheter pulmonary valve. Of sixty-six enrolled participants, 21 patients were approved for implant and 20 received the Harmony device. Most patients had been diagnosed with tetralogy of Fallot and had augmented RVOTs or transannular patch repairs. Clinical assessments were collected at baseline and after one-month, three-month and six-month follow-ups. In the 20 implanted patients, the device was implanted in the intended location; however, proximal migration occurred in one participant during delivery system removal. Two devices were surgically explanted. Premature ventricular contractions related to the procedure were reported in three patients; two were resolved without treatment. One patient had ventricular arrhythmias that required treatment and were later resolved. Eighteen patients returned for the three- and six-month follow-up assessments. Echocardiographic data remained consistent with those observed at the one-month visit. Compared with baseline, patients had significant improvements in pulmonary regurgitation. By the six-month follow-up, there were minimal changes in incidence of paravalvular leak, mean RVOT gradient or tricuspid regurgitation. Study limitations include lack of randomization, control group, and small sample size. Additionally, enrollment was limited to three sites, each with an experienced catheterization cardiologist performing the procedure. The authors noted that further studies with larger patient populations are needed to assess long-term durability, function and safety of the Harmony device.

Melody

McElhinney et al. (2010) conducted a single-arm multicenter trial of 136 patients (median age, 19 years) who underwent catheterization for intended Melody valve implantation. Implantation was attempted in 124 patients. In the other 12, transcatheter pulmonary valve placement was not attempted because of the risk of coronary artery compression (n = 6) or other clinical or protocol contraindications. There was 1 death and 1 explanted valve after conduit rupture. The median peak RVOT gradient was 37 mmHg before implantation and 12 mmHg immediately after implantation. Before implantation, pulmonary regurgitation was moderate or severe in 92 patients. No patient had more than mild pulmonary regurgitation early after implantation or during follow-up. Freedom from stent fracture was 77.8 +/-4.3% at 14 months. Freedom from valve dysfunction or reintervention was 93.5 +/-2.4% at 1 year. A higher RVOT gradient at discharge and younger age were associated with shorter freedom from dysfunction. The results demonstrated an ongoing high rate of procedural success and encouraging short-term valve function. All re-interventions in this series were for RVOT obstruction, highlighting the importance of patient selection, adequate relief of obstruction, and measures to prevent and manage stent fracture. Jones et al. (2022) reported on 58 patients at 10 years. The estimated freedom from mortality was 90%, from reoperation 79%, and from any reintervention 60%. Ten-year freedom from TPV dysfunction was 53% and was significantly shorter in children than in adults. Estimated freedom from TPV-related endocarditis was 81% at 10 years, with an annualized rate of 2.0% per patient-year. NCT00740870.

SAPIEN

Kenny et al. (2018) reported three-year follow-up results of the COMPASSION (Congenital Multicenter Trial of Pulmonic Valve Regurgitation Studying the SAPIEN Transcatheter Heart Valve) trial. Patients with moderate to severe pulmonary regurgitation and/or RVOT conduit obstruction were implanted with the SAPIEN transcatheter heart valve. Fifty-seven of the 63 eligible patients were accounted for at the three-year follow-up visit from a total of 69 implantations in 81 enrolled patients. Indications for implantation were pulmonary stenosis (7.6%), regurgitation (12.7%) or both (79.7%). Functional improvement in NYHA functional class was observed in 93.5% of patients. Mean peak conduit gradient decreased from 37.5 ±25.4 to 17.8 ±12.4 mmHg, and mean right ventricular systolic pressure decreased from 59.6 ±17.7 to 42.9 ±13.4 mmHg. Pulmonary regurgitation was mild or less in 91.1% of patients. When implanted in patients with moderate to severe pulmonary regurgitation and/or RVOT conduit obstruction, the SAPIEN valve was associated with favorable outcomes at three years, with low rates of all-cause mortality, reintervention and endocarditis and no stent fractures.

Tricuspid Valve

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of transcatheter procedures for treating tricuspid valve disease. Further results from prospective, randomized controlled trials are needed to determine safety, efficacy, durability and the ideal candidates for the procedure.

Bugan et al. (2022) completed a systematic review and meta-analysis to evaluate the feasibility of orthotopic transcatheter tricuspid valve replacement (TTVR) devices, echocardiographic, functional improvements, and mortality rates following replacement in patients with significant tricuspid valve regurgitation. The authors systematically searched for the studies evaluating the efficacy and safety of transcatheter tricuspid valve replacement for significant tricuspid valve regurgitation. The efficacy and safety outcomes were the improvements in New York Heart Association functional class, 6-minute walking distance, all-cause death, and periprocedural and long-term complications. In addition, a random-effect meta-analysis was performed comparing outcomes before and after transcatheter tricuspid valve replacement. Nine studies with 321 patients were included in this study. The mean age was 75.8 years, and the mean European System for Cardiac Operative Risk Evaluation II score was 8.2% (95% CI: 6.1 to 10.3). Severe, massive, and torrential tricuspid valve regurgitation was diagnosed in 95% of patients (95% CI: 89% to 98%), and 83% (95% CI: 73% to 90%) of patients were in New York Heart Association functional class III or IV. At a weighted mean follow-up of 122 days, New York Heart Association functional class (risk ratio = 0.20; 95% CI: 0.11 to 0.35; p < .001) and 6-minute walking distance (mean difference = 91.1 m; 95% CI: 37.3 to 144.9 m; p < .001) improved. The prevalence of severe or greater tricuspid valve regurgitation was reduced after transcatheter tricuspid valve replacement (baseline risk ratio = 0.19; 95% CI: 0.10 to 0.36; p < .001). In total, 28 patients (10%; 95% CI: 6% to 17%) died. Pooled analyses demonstrated non-significant differences in hospital and 30-day mortality and > 30-day mortality than predicted operative mortality (risk ratio = 1.03; 95% CI: 0.41 to 2.59; p = .95, risk ratio = 1.39; 95% CI: 0.69 to 2.81; p = .35, respectively). The authors concluded that transcatheter tricuspid valve replacement could be an emerging treatment option for patients with severe tricuspid regurgitation who are not eligible for transcatheter repair or surgical replacement because of high surgical risk. Limitations include a potential for bias as the analysis only included single-arm interventional studies case series, and no randomized controlled trials (RCTs). Moderate heterogeneity was found in the consistency of results. In addition, there are no specific guideline recommendations for patient selection for TTVR, therefore, this meta-analysis is limited by the lack of

uniformity in the definition of procedural success. Further research with randomized controlled trials is needed to validate these findings.

An ECRI Clinical Evidence Assessment found very low quality evidence on percutaneous tricuspid valve repair for treating TR in patients who are ineligible for surgery. Study results were at high risk of bias due to small sample size and lack of controls and randomization (ECRI, 2022).

Bocchino et al. (2021) performed a meta-analysis to assess the pooled clinical and echocardiographic outcomes of different isolated transcatheter tricuspid valve repair strategies for moderate or greater TR in patients who were ineligible for surgery. Fourteen observational studies (n = 771) were included. At a mean follow-up of 212 days, 209 patients (35%) were in NYHA functional class III or IV compared with 586 patients (84%) at baseline. Six-minute walking distance significantly improved by a mean 50 meters. One hundred forty-seven patients (24%) showed severe or greater TR after isolated transcatheter tricuspid valve repair compared with 616 (96%) at baseline. The included studies are at a high risk of bias due to several factors: small sample size, single-center focus, retrospective design, and/or lack of controls, randomization and blinding. Further results from prospective, randomized controlled trials are needed to confirm these findings.

The international TriValve Registry (n = 312) was developed to evaluate several transcatheter tricuspid valve interventions in high-risk patients with severe TR (predominantly functional). Interventions included leaflet repair, annulus repair, coaptation and replacement. Implanted devices included MitraClip (n = 210), Trialign (n = 18), TriCinch first generation (n = 14), caval valve implantation (n = 30), FORMA (n = 24), Cardioband (n = 13), NaviGate (n = 6) and PASCAL (n = 1). Preliminary results of transcatheter tricuspid valve interventions were promising in terms of safety and feasibility. Mid-term survival was favorable in this high-risk population. However, long-term outcomes and better patient selection are needed to better understand the clinical role of these procedures for treating TR (Taramasso et al., 2019).

In an observational study of 64 consecutive patients, Nickenig et al. (2017) evaluated the safety and feasibility of transcatheter repair of chronic severe TR using edge-to-edge clipping. The procedure was successfully performed in 97% of the patients. After the procedure, TR was reduced by at least one grade in 91% of the patients, with significant improvements in NYHA class and 6-minute walk test. In 13% of patients, TR remained severe after the procedure. Significant reductions in effective regurgitant orifice area, vena contracta width and regurgitant volume were observed. This study is limited by small sample size, lack of randomization and control and limited follow-up.

Valve-in-Valve (ViV) Procedures

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of ViV procedures for mitral, pulmonary, or tricuspid valves. The evidence for these procedures is still evolving. Evidence supporting ViV procedures for aortic valves is stronger.

Al-Abcha et al. (2021) performed a meta-analysis to compare clinical outcomes of ViV TAVR versus redo SAVR in failed bioprosthetic aortic valves. Twelve observational studies were included (n = 8,430). Compared to redo SAVR, ViV TAVR was associated with a similar risk of all-cause mortality, cardiovascular mortality, myocardial infarction, permanent pacemaker implantation, and the rate of moderate to severe paravalvular leakage. However, the rates of major bleeding, stroke, procedural mortality and 30-day mortality were significantly lower in the ViV group. Randomized clinical trials are needed to confirm the safety and efficacy of ViV TAVR in patients with failed bioprosthetic aortic valves.

Gozdek et al. (2018) performed a systematic review and meta-analysis to compare redo SAVR with ViV TAVR for patients with failed aortic bioprostheses. Five observational studies (n = 342) were included in the analysis. Although there was no statistical difference in procedural mortality, 30-day mortality, and cardiovascular mortality at a mean follow-up period of 18 months, cumulative survival analysis favored surgery. ViV procedures were associated with a significantly lower rate of permanent pacemaker implantations and shorter intensive care unit and hospital stays. Redo SAVR offered superior echocardiographic outcomes, lower incidence of patient-prosthesis mismatch, fewer paravalvular leaks, and lower mean postoperative aortic valve gradients. The authors concluded that ViV approach is a safe, feasible alternative to conventional surgery that may offer an effective, less invasive treatment for patients with failed surgical aortic bioprostheses who are inoperable or at high risk, but that SAVR should remain the standard of care, particularly in the low-risk population, because it offers superior hemodynamic outcomes with low mortality rates.

Tam et al. (2018) performed a systematic review and meta-analysis to determine the safety and efficacy of ViV TAVR versus redo SAVR for the treatment of previously failed aortic bioprostheses. Four unadjusted (n = 298) and two propensity-matched (n = 200) observational studies were included. Despite higher predicted surgical risk of ViV patients, there was no difference in perioperative mortality (4.4% versus 5.7%) or late mortality, reported at median one-year follow-up. The incidence of permanent pacemaker implantation (8.3% versus 14.6%) and dialysis (3.2% versus 10.3%) were lower in ViV. There was a reduction in the incidence of severe patient-prosthesis mismatch (3.3% versus 13.5%) and mild or greater paravalvular leak (5.5% versus 21.1%) in the redo SAVR group compared to ViV.

Using patient data from the STS/American College of Cardiology Transcatheter Valve Therapy Registry, Tuzcu et al. (2018) evaluated the safety and effectiveness of ViV TAVR for failed surgically implanted bioprostheses by comparing it with the benchmark of native valve (NV) TAVR. Patients who underwent ViV TAVR (n = 1,150) were matched 1:2 to patients undergoing NV TAVR (n = 2,259). Unadjusted analysis revealed lower 30-day mortality (2.9% vs. 4.8%), stroke (1.7% vs. 3.0%) and heart failure hospitalizations (2.4% vs. 4.6%) in the ViV TAVR compared with the NV TAVR group. Adjusted analysis revealed lower 30-day mortality, lower one-year mortality and hospitalization for heart failure in the ViV TAVR group. Patients in the ViV TAVR group had higher post-TAVR mean gradient (16 vs. 9 mm Hg), but less moderate or severe aortic regurgitation (3.5% vs. 6.6%). Post-TAVR gradients were highest in small SAVRs and stenotic SAVRs.

Eleid et al. (2017) reported one-year outcomes of percutaneous balloon-expandable transcatheter heart valve implantation in a failed mitral bioprosthesis (n = 60), previous ring annuloplasty (n = 15) and severe mitral annular calcification (n = 12). Acute procedural success was achieved in 97% of the ViV group and 74% in the valve in ring/valve in mitral annular calcification (MAC) group. Thirty-day survival free of death and cardiovascular surgery was 95% in the ViV subgroup and 78% in the valve in ring/valve in MAC group. One-year survival free of death and cardiovascular surgery was 86% in the ViV group compared with 68%. At one year, 90% had NYHA functional class I or II symptoms, no patients had more than mild residual mitral prosthetic or periprosthetic regurgitation and the mean transvalvular gradient was 7 ±3 mm Hg. The procedure for failed annuloplasty rings and severe MAC was feasible but associated with significant rates of left ventricular outflow tract obstruction, need for a second valve and/or cardiac surgery. This study reflects very early results with the procedure and is limited by small sample size and lack of randomization . Further studies of a larger number of patients treated using similar techniques and with longer follow-up duration will be necessary to continually assess outcomes of this novel therapy.

In an observational study, Yoon et al. (2017) evaluated the outcomes of TMVR in 248 patients with failed mitral bioprosthetic valves (ViV) and annuloplasty rings. The TMVR procedure provided acceptable outcomes in high-risk patients with degenerated bioprostheses or failed annuloplasty rings, but mitral valve-in-ring was associated with higher rates of procedural complications and mid-term mortality compared with mitral ViV. This study is limited by lack of randomization and control. Further studies evaluating the long-term outcomes of patients undergoing TMVR for degenerated bioprostheses or failed annuloplasty rings are needed.

Deeb et al. (2017) evaluated the safety and effectiveness of the CoreValve in patients with failed surgical aortic bioprostheses. The CoreValve U.S. Expanded Use Study was a prospective, nonrandomized study that enrolled 233 patients with symptomatic surgical valve failure who were deemed unsuitable for reoperation. Patients were treated with the CoreValve and evaluated for 30-day and one-year outcomes after the procedure. Surgical valve failure occurred through stenosis (56.4%), regurgitation (22.0%) or a combination (21.6%). A total of 227 patients underwent attempted TAVR and successful TAVR was achieved in 225 (99.1%) patients. Patients were elderly (76.7 ±10.8 years), had a STS PROM score of 9.0 ±6.7% and were severely symptomatic (86.8% NYHA functional class III or IV). The all-cause mortality rate was 2.2% at 30 days and 14.6% at one year; major stroke rate was 0.4% at 30 days and 1.8% at one year. Moderate aortic regurgitation occurred in 3.5% of patients at 30 days and 7.4% of patients at one year, with no severe aortic regurgitation. The rate of new permanent pacemaker implantation was 8.1% at 30 days and 11.0% at one year. The mean valve gradient was 17.0 ±8.8 mmHg at 30 days and 16.6 ±8.9 mmHg at one year.

Webb et al. (2017) evaluated 30-day and one-year outcomes in high-risk patients undergoing ViV TAVR using the SAPIEN XT valve. Patients with symptomatic degeneration of surgical aortic bioprostheses at high risk (≥ 50% major morbidity or mortality) for reoperative surgery were prospectively enrolled in the multicenter PARTNER 2 ViV trial and continued access registries. ViV procedures were performed in 365 patients (96 initial registry, 269 continued access patients). Mean age was 78.9 ±10.2 years, and mean STS score was 9.1 ±4.7%. At 30 days, all-cause mortality was 2.7%, stroke was 2.7%, major vascular complication was 4.1%, conversion to surgery was 0.6%, coronary occlusion was 0.8% and new pacemaker insertion was 1.9%. One-year all-cause mortality was 12.4%. Mortality fell from the initial registry to the subsequent continued access registry, both at 30 days

(8.2% vs. 0.7%, respectively) and at one year (19.7% vs. 9.8%, respectively). At one-year, mean gradient was 17.6 mmHg, and effective orifice area was 1.16 cm2, with greater than mild paravalvular regurgitation of 1.9%. LVEF increased (50.6% to 54.2%), and mass index decreased (135.7 to 117.6 g/m2), with reductions in both mitral (34.9% vs. 12.7%) and tricuspid (31.8% vs. 21.2%) moderate or severe regurgitation.

Phan et al. (2016) conducted a systematic review to compare outcomes and safety of transcatheter ViV implantation with reoperative conventional aortic valve replacement. A total of 18 relevant observational studies (823 patients) were included. Pooled analysis suggested that transcatheter ViV implantation achieved similar hemodynamic outcomes, with lower risk of strokes and bleeding, but higher rates of paravalvular leaks compared to reoperative conventional aortic valve replacement. The authors noted that future randomized studies and prospective registries are essential to compare the effectiveness of these procedures.

Using VIVID registry data, Dvir et al. (2014) determined the survival of patients after transcatheter aortic ViV implantation inside failed surgical bioprosthetic valves. Correlates for survival were evaluated using a multinational registry that included 459 patients with degenerated bioprosthetic valves undergoing ViV implantation. Modes of bioprosthesis failure were stenosis (n = 181), regurgitation (n = 139) and combined (n = 139). The stenosis group had a higher percentage of small valves (37% vs 20.9% and 26.6% in the regurgitation and combined groups, respectively). Within one month following ViV implantation, 35 (7.6%) patients died, 8 (1.7%) had major stroke and 313 (92.6%) of surviving patients had good functional status (NYHA class I/II). The overall one-year survival rate was 83.2%; 62 death events; 228 survivors). Patients in the stenosis group had worse one-year survival (76.6%; 34 deaths; 86 survivors) in comparison with the regurgitation group (91.2%; 10 deaths; 76 survivors) and the combined group (83.9%; 18 deaths; 66 survivors). Similarly, patients with small valves had worse one year survival (74.8%; 27 deaths; 57 survivors) versus with intermediate-sized valves (81.8%; 26 deaths; 92 survivors) and with large valves (93.3%; seven deaths; 73 survivors). Factors associated with mortality within one year included having small surgical bioprosthesis (≤ 21 mm) and baseline stenosis (vs regurgitation). In a follow-up study, Bleiziffer et al. (2020) assessed long-term survival and reintervention outcomes after transcatheter aortic ViV procedures. A total of 1,006 aortic ViV procedures were included in the analysis. The primary endpoint was patient survival, and the main secondary endpoint was all-cause reintervention. Results showed that the size of the original failed valve may influence long-term mortality, and the type of transcatheter valve may influence the need for reintervention after aortic ViV procedures.

Cerebral Protection

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of transcatheter cerebral protection devices in improving neurological and cognitive function following transcatheter aortic valve replacement.

A prospective, post-market, multi-center, randomized controlled trial was conducted by Kapadia et al. (2022) to evaluate the Sentinel cerebral embolic protection (CEP) device in patients with aortic stenosis undergoing transfemoral transcatheter TAVR. A total of 3,000 patients with aortic stenosis across North America, Europe, and Australia underwent randomization in a 1:1 ratio to undergo transfemoral TAVR with CEP (CEP group) or without CEP (control group); 1,501 were assigned to the CEP group and 1499 to the control group. The primary end point was stroke within 72 hours after TAVR or before discharge (whichever came first) in the intention-to-treat population. Disabling stroke, death, transient ischemic attack, delirium, major or minor vascular complications at the CEP access site, and acute kidney injury were also assessed. A neurology professional examined all enrolled study patients at baseline and again after TAVR. A CEP device was successfully deployed in 1,406 of the 1,489 patients (94.4%) in whom an attempt was made. The incidence of stroke within 72 hours after TAVR or before discharge did not differ between the CEP group and the control group (2.3% vs. 2.9%; difference, −0.6 percentage points; 95% confidence interval, −1.7 to 0.5; p = 0.30). Disabling stroke occurred in 0.5% of the patients in the CEP group and in 1.3% of those in the control group. There were no sizeable differences between the CEP group and the control group in the percentage of patients who died (0.5% vs. 0.3%); had a stroke, a transient ischemic attack, or delirium (3.1% vs. 3.7%); or had acute kidney injury (0.5% vs. 0.5%). One patient (0.1%) had a vascular complication at the CEP access site. The authors concluded among patients with aortic stenosis undergoing transfemoral TAVR, the use of CEP did not influence the incidence of periprocedural stroke but based on the 95% confidence interval around this outcome, the results may not rule out a benefit of CEP during TAVR. Limitations include a greater percentage of female patients in the CEP group despite randomization and large number of enrolled patients. Female sex has been reported to be a risk factor for stroke with TAVR. Granular data on clinical outcomes were restricted to a small number of endpoints, with only short-term follow-up. In addition, the trial results apply only to the Sentinel CEP device and cannot be generalized to other CEP devices. There are additional ongoing clinical trials including the BHF PROTECT-TAVI (British Heart Foundation Randomized Trial of Routine Cerebral Embolic Protection in Transcatheter

Aortic Valve Implantation; ISRCTN Registry number, ISRCTN16665769) in which additional data on the effectiveness of CEP during TAVR are forthcoming.

In a letter to the editor, Radwan et al. (2021) performed a meta-analysis of studies evaluating the safety and efficacy of the Sentinel cerebral protection system during TAVR. Three RCTs and four observational studies were included (n = 117,329). The Sentinel group was associated with lower risk of 30-day stroke, mortality and major bleeding. These short-term results were mainly driven from observational data as subgroup analysis from the RCTs showed a trend toward benefit without statistical significance. The rate of major vascular complications was similar between the 2 groups. Results from large RCTs are needed to confirm these results.

Ndunda et al. (2019) performed a systematic review and meta-analysis to compare the clinical outcomes following TAVR with and without the use of the Sentinel Cerebral Protection System (Sentinel CPS). Four studies (three RCTs and one propensity score-matched cohort study) comparing patients undergoing TAVR with Sentinel CPS (n = 606) to those without any embolic protection device (n = 724) were included. Sentinel CPS use was associated with lower rates of 30-day mortality, 30-day symptomatic stroke and major or life-threatening bleeding. There was no significant difference between the two arms in the incidence of acute kidney injury and major vascular complications. The authors noted limitations for the analyzed studies including lack of a control group for some studies, small sample sizes, lack of patient-level data and missing outcomes data. Furthermore, not all included studies were randomized.

An ECRI product brief on the Sentinel device reported that the evidence suggests that device placement is relatively safe, but whether it benefits patients undergoing TAVR is unclear. Studies reported inconsistent findings on the device's impact on reducing stroke risk and too few data are available on the long-term neurocognitive burden of brain microinfarction in patients treated with the device. Additional controlled studies that report on these outcomes are needed to assess the device's effectiveness (ECRI, 2017b; updated 2019).

Bagur et al. (2017) performed a systematic review and meta-analysis evaluating the impact of embolic protection devices on cerebrovascular events during TAVR. Sixteen studies(5 RCTs and 11 observational studies) involving 1,170 patients (865/305 with/without embolic protection devices) were included. The embolic protection device delivery success rate was reported in all studies and was achieved in 94.5% of patients. Meta-analyses comparing the two methods showed no significant differences between patients undergoing TAVR with or without embolic protection devices with respect to clinically evident stroke and 30-day mortality. Embolic protection during TAVR may be associated with smaller volume of silent ischemic lesions and smaller total volume of silent ischemic lesions. However, it may not reduce the number of new-single, multiple or total number of lesions.

In an observational cohort study, Seeger et al. (2017) evaluated the impact of cerebral embolic protection on stroke-free survival in 802 consecutive patients undergoing TAVR for severe aortic stenosis. The Sentinel cerebral embolic protection device was used in 34.9% (n = 280) of patients. In the remaining group of patients, TAVR was performed without cerebral embolic protection. In patients undergoing TAVR, use of a cerebral embolic protection device demonstrated a significantly higher rate of stroke-free survival compared with unprotected TAVR. This study is limited by lack of randomization.

In two randomized, controlled trials (Kapadia et al., 2017; Van Mieghem et al., 2016), the primary efficacy endpoint was reduction in volume of new cerebral lesions on diffusion-weighted magnetic resonance imaging (DW-MRI) evaluation up to seven days post-TAVR, a surrogate endpoint for cerebral damage. This endpoint was not met in either trial, although both trials demonstrated a nonsignificant numerical reduction in new cerebral lesions favoring the Sentinel device over no transcatheter cerebral embolic protection. In addition, both trials were limited by small sample sizes and poor compliance with DW-MRI follow-up, which was missing for 21% of SENTINEL trial patients (Kapadia et al., 2017) and 43% of MISTRAL-C trial patients (Van Mieghem et al., 2016).

In the Claret Embolic Protection and TAVI (CLEAN-TAVI) trial, Haussig et al. (2016) evaluated the effect of a cerebral protection device on the number and volume of cerebral lesions in patients undergoing TAVR. One hundred patients were randomly assigned to undergo TAVR with a cerebral protection device (filter group; n = 50) or without a cerebral protection device (control group; n = 50). Brain MRI was performed at baseline, two days and seven days after TAVR. The use of a cerebral protection device reduced the frequency of ischemic cerebral lesions in potentially protected regions. The number of new lesions was 4.00 in the filter group and 10.00 in the control group. New lesion volume after TAVR was 242 mm^3 in the filter group and 527 mm^3 in the control group. One patient in the control group died prior to the 30-day visit. Life-threatening

hemorrhages occurred in one patient in the filter group and one in the control group. Major vascular complications occurred in five patients in the filter group and six patients in the control group. One patient in the filter group and five in the control group had acute kidney injury, and three patients in the filter group had a thoracotomy. Larger studies, with longer follow-up are needed to assess the effect of cerebral protection device use on neurological and cognitive function after TAVR. NCT01833052.

Giustino et al. (2016) conducted a systematic review and meta-analysis of four randomized controlled trials (n = 252) that tested the safety and efficacy of embolic protection during TAVR. Use of embolic protection was associated with lower total lesion volume and smaller number of new ischemic lesions. Embolic protection was associated with a trend toward lower risk for deterioration in National Institutes of Health Stroke Scale score at discharge and higher Montreal Cognitive Assessment score. Risk for overt stroke and all-cause mortality were not significantly lower in the embolic protection group. The authors noted that the findings are subject to the inherent limitations of the included trials due to study design, length of follow-up, imaging and neurocognitive assessment dropout. Some of the endpoints were not available in all of the included trials. Most of the valves used were first-generation TAVR devices. Given the substantial limitations of the included studies, the results are only hypothesis generating. Further prospective, adequately powered randomized controlled trials are needed to establish the role of embolic protection during TAVR.

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)

ACC/AHA guidelines for the management of patients with valvular heart disease (Otto et al., 2020) make the following recommendations regarding transcatheter valve therapies:

Aortic

In patients with an indication for aortic valve replacement, the choice of prosthetic valve should be based on a shared decision-making process that accounts for the patient's values and preferences and includes discussion of the indications for and risks of anticoagulant therapy and the potential need for and risks associated with valve reintervention.

Bicuspid Aortic Valve

2020 ACC/AHA guideline (updated 2021) for intervention recommends patients with BAV and severe AR who meet criteria for AVR, aortic valve repair may be considered in selected patients if the surgery is performed at a Comprehensive Valve Center. In patients with BAV and symptomatic, severe AS, TAVI may be considered as an alternative to SAVR after consideration of patient-specific procedural risks, values, trade-offs, and preferences, and when the surgery is performed at a Comprehensive Valve Center. RCTs are needed to obtain full clarity on the optimal use of TAVI in this population, as well as long-term outcomes.

Mitral

In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least one year.

In patients with chronic severe secondary MR related to left ventricular systolic dysfunction (LVEF < 50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal guideline-directed management and therapy for heart failure, transcatheter edge-to-edge repair is reasonable in patients with appropriate anatomy as defined on transesophageal echocardiography and with LVEF between 20% and 50%, left ventricular end-systolic dimension ≤ 70 mm, and pulmonary artery systolic pressure ≤ 70 mmHg.

Pulmonary

Transcatheter pulmonary valve replacement is outside the scope of these guidelines. Refer to Stout et al., 2019.

Tricuspid

The guideline does not address the transcatheter approach for tricuspid valve replacement.

ViV

For severely symptomatic patients with bioprosthetic aortic valve stenosis and high or prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a Comprehensive Valve Center.

For patients with severe heart failure symptoms caused by bioprosthetic valve regurgitation who are at high to prohibitive surgical risk, a transcatheter ViV procedure is reasonable when performed at a Comprehensive Valve Center.

The ACC and STS, along with the Society for Cardiovascular Angiography and Interventions (SCAI) and the American Association for Thoracic Surgery (AATS), released an expert consensus statement outlining operator and institutional recommendations and requirements for creating and maintaining transcatheter aortic valve replacement programs. The recommendations are aimed at ensuring optimal patient care (Bavaria et al., 2018). The same organizations released similar statements addressing transcatheter therapies for mitral valve procedures (Bonow et al., 2020) and pulmonary valve procedures (Hijazi et al., 2015).

ACC guidelines on the management of adults with congenital heart disease address interventions for patients with RVOT dysfunction. Interventions include surgical replacement or percutaneous stenting and/or transcatheter valve placement. Patients with moderate or greater conduit stenosis and/or regurgitation who have reduced exercise capacity or arrhythmias can benefit from surgical or transcatheter conduit intervention to relieve stenosis and/or regurgitation. Transcatheter stenting and pulmonary valve replacement may be performed with high procedural success and low mortality rates, and result in improved hemodynamics and improved exercise capacity. Surgical conduit replacement carries a higher risk of periprocedural complications with good long-term outcomes. Predictors of conduit dysfunction and reoperation include placement of small diameter conduits; therefore, insertion of conduits with the largest possible diameter should be attempted, anticipating that subsequent valve replacement may be via a transcatheter approach (Stout et al., 2019).

ACC appropriate use criteria for the treatment of severe aortic stenosis include criteria for patients with LFLG-AS (Bonow et al., 2017).

European Society of Cardiology (ESC)

ESC guidelines for the management of adult congenital heart disease state that transcatheter pulmonary valve implantation techniques are an alternative to open heart surgery in patients with RVOT conduit stenosis/regurgitation. Transcatheter replacement, when technically feasible, provides outcomes comparable to surgical pulmonary valve replacement and is intended to extend the lifetime of a conduit, reducing the number of reoperations during a patient's lifetime (Baumgartner et al., 2020).

European Society of Cardiology (ESC)/European Association for Cardio-Thoracic Surgery (EACTS)

In their joint guideline for the management of valvular heart disease, the ESC and the EACTS (Vahanian, 2022) recommend the following with regard to transcatheter heart valve procedures:

Aortic

The guideline recommends that the choice between surgical and transcatheter intervention for aortic stenosis be based upon careful evaluation of clinical, anatomical and procedural factors by the cardiac treatment team, weighing the risks and benefits of each approach for the individual patient.

They recommend SAVR in younger patients who are low risk for surgery (< 75 years and STSPROM/ EuroSCORE II < 4%) or in patients who are operable and unsuitable for transfemoral TAVI; however, they recommend TAVI for older patients (≥ 75 years), or for those who are high-risk (STS-PROM/EuroSCORE II > 8%) or unsuitable for surgery. SAVR or TAVI are recommended for remaining patients according to individual clinical, anatomical and procedural characteristics.

Tricuspid

The guideline indicates that transcatheter treatment of symptomatic secondary severe tricuspid regurgitation has a IIb recommendation which indicates the procedure may be considered in inoperable patients at a heart valve center with expertise in the treatment of tricuspid valve disease. This level of recommendation indicates that the usefulness or efficacy of this approach is less well established by evidence/opinion.

National Institute for Health and Care Excellence (NICE)

NICE published an interventional procedures guidance (IPG) for transcatheter tricuspid valve annuloplasty for tricuspid regurgitation in which they state that the evidence on efficacy of transcatheter tricuspid valve annuloplasty is limited in quantity and quality and that the evidence on safety shows there are serious but well-recognized complications when this procedure is done on people with severe and symptomatic tricuspid regurgitation. For people with mild or moderate tricuspid regurgitation, the evidence is inadequate in quantity and quality on the safety and efficacy of this procedure (NICE, 2022a).

In another IPG published by NICE that addresses transcatheter tricuspid valve leaflet repair for tricuspid regurgitation, NICE states that the evidence on efficacy of transcatheter valve leaflet repair is limited in quantity and quality for people with severe and symptomatic tricuspid regurgitation. The IPG also states that the evidence on its safety shows there are serious but well-recognized complications. For people with mild or moderate tricuspid regurgitation, the IPG states that the evidence is inadequate in quantity and quality for the safety and efficacy of transcatheter tricuspid valve leaflet repair (NICE, 2022b).

NICE published an overarching guideline for heart valve disease presenting in adults. In the evidence review supporting documentation for the guideline, NICE states that transcatheter valve interventions may allow for quicker recovery if the procedure is uncomplicated and notes that the abnormal valve is not removed using the transcatheter approach, rather, the abnormal valve is pushed aside to allow for the prosthetic valve to be implanted.

For aortic valve disease, this guideline states that TAVI is clinically effective but not currently cost effective for patients defined as intermediate or low risk for cardiac surgery for aortic valve disease. For aortic stenosis, the guideline states that transcatheter interventions are currently only indicated for symptomatic patients; however, for aortic regurgitation, there is no current accepted transcatheter intervention. The guideline also stated that there is no evidence for TAVI valve durability beyond 6-7 years and that there is evidence of valve leaflet deterioration due to crimping which cannot be avoided when a valve is implanted through a catheter.

With regard to mitral stenosis, this guideline on heart valve disease in adults recommends transcatheter valvotomy for adults with rheumatic severe mitral stenosis if the valve is suitable for the procedure or surgical mitral valve replacement when the transcatheter valvotomy is not suitable. Transcatheter edge-to-edge repair is recommended, if suitable, for adults with severe primary mitral regurgitation and symptoms when surgery is unsuitable and for adults with heart failure and severe secondary mitral regurgitation if surgery is unsuitable and the patient remains symptomatic on medical management.

The guideline does not include any guidance for transcatheter tricuspid valve repair for tricuspid regurgitation (NICE, 2021a).

A NICE guidance document states that the current evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis shows some serious but well-recognized complications. Evidence on its efficacy is limited in quality. This procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2021).

A NICE IPG on the transapical transcatheter mitral valve-in-ring implantation procedure states that the evidence on the safety of this procedure after failed mitral valve repair surgery is adequate and shows some serious but well recognized complications. It also states that the evidence on this procedure's efficacy is limited in quality and that the procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2021c).

A NICE guidance document states that the evidence on the safety and efficacy of ViV TAVR for aortic bioprosthetic dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. The report also notes that long-term evidence for ViV TAVR is from earlier-generation devices. The technology is evolving, and longer-term evidence is needed (NICE, 2019a).

A NICE guidance document states that transcatheter insertion of a cerebral protection device to prevent cerebral embolism during TAVR raises no major safety concerns other than those associated with the TAVR procedure. However, the evidence on efficacy for preventing TAVR-related stroke is inconclusive. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2019b).

A NICE guidance document states that evidence on the safety and efficacy of percutaneous mitral valve leaflet repair for mitral regurgitation is adequate to support the use of this procedure, in patients for whom open surgery is contraindicated following risk assessment, provided that standard arrangements are in place for clinical governance, consent and audit (NICE, 2019c).

A NICE guidance document states that the evidence on the safety and efficacy of TAVR for aortic stenosis is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Patient details should be entered into the national registry and adverse events should be reported. Patient selection should be carried out by an experienced multidisciplinary team, which must include interventional cardiologists experienced in the procedure, cardiac surgeons, an expert in cardiac imaging and, when appropriate, a cardiac anesthetist and a specialist in elderly medicine. The multidisciplinary team should determine the risk level for each patient and the TAVR device most suitable for them (NICE, 2017).

A NICE guidance document states that the evidence on percutaneous pulmonary valve implantation (PPVI) for RVOT dysfunction shows good short-term efficacy. There is little evidence on long-term efficacy, but it is well documented that these valves may need to be replaced in the longer term. With regard to safety there are well-recognized complications, particularly stent fractures in the longer term, which may or may not have clinical effects. Patients having this procedure are often very unwell and might otherwise need open heart surgery (typically reoperative) with its associated risks (NICE, 2013).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Aortic

SAPIEN

The Edwards SAPIEN Transcatheter Heart Valve received FDA premarket approval (P100041) on November 2, 2011. The device is indicated for transfemoral delivery in patients with severe, symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis. The device is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections. Labeling also states that implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon aortic valvuloplasty. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100041. (Accessed September 21, 2022)

On October 19, 2012, the FDA approved an expanded indication for the Edwards SAPIEN valve to include patients with aortic stenosis who are eligible for surgery but who are at high risk for serious surgical complications or death (P110021). In this patient group, the valve is approved for both transfemoral and transapical delivery. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P110021. (Accessed September 21, 2022)

On September 23, 2013, the FDA approved revised labeling for the SAPIEN valve. The new labeling removes references to specific access points now making the device available for inoperable patients who need an alternate access point. The device is now indicated for patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction > 20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to be: 1) inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis; or 2) be operative candidates for aortic valve replacement but who have a predicted operative risk score ≥ 8% or are judged by the heart team to be at a ≥ 15% risk of mortality for SAVR.

SAPIEN XT, SAPIEN 3, and SAPIEN 3 Ultra

The Edwards SAPIEN XT Transcatheter Heart Valve and accessories received FDA premarket approval (P130009) on June 16, 2014. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area ≤ 1.0 cm2 or aortic valve area index ≤ 0.6 cm2/m2, a mean aortic valve gradient of ≥ 40 mmHg or a peak aortic-jet velocity of ≥ 4.0 m/s), and with native anatomy appropriate for the 23, 26 or 29 mm valve system, who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., STS operative

risk score ≥ 8% or at a ≥ 15% risk of mortality at 30 days). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130009. (Accessed September 21, 2022)

The Edwards SAPIEN 3 Transcatheter Heart Valve and accessories received FDA premarket approval (P140031) on June 17, 2015. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., STS operative risk score ≥ 8% or at a ≥ 15% risk of mortality at 30 days). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031. (Accessed September 21, 2022)

On August 18, 2016, the FDA granted expanded approval of the SAPIEN XT and SAPIEN 3 valves to include patients with intermediate surgical risk for aortic valve replacement.

CoreValve

The Medtronic CoreValve System received FDA premarket approval (P130021) on January 17, 2014. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area ≤ 0.8 cm2, a mean aortic valve gradient of > 40 mm Hg, or a peak aortic-jet velocity of > 4.0 m/s) and with native aortic annulus diameters between 18 and 29 mm who are judged by a heart team, including a cardiac surgeon, to be at extreme risk or inoperable for open surgical therapy (predicted risk of operative mortality and/or serious irreversible morbidity ≥ 50% at 30 days). The device is contraindicated for patients presenting with any of the following conditions:

- Known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (titanium or nickel), or sensitivity to contrast media, which cannot be adequately premedicated
- Ongoing sepsis, including active endocarditis
- Preexisting mechanical heart valve in aortic position

Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021. (Accessed September 21, 2022)

On June 12, 2014, the FDA approved an expanded indication for the Medtronic CoreValve System to include patients at high or greater risk for open surgical therapy (i.e., STS operative risk score > = 8% or at a > = 15% risk of mortality at 30 days).

On June 22, 2015, the FDA approved Medtronic's next-generation CoreValve Evolut™ R System which allows for the device to be recaptured and repositioned.

On March 20, 2017, the FDA approved Medtronic's CoreValve Evolut PRO valve for the treatment of severe aortic stenosis in symptomatic patients who are at high or extreme risk for open heart surgery. The valve design includes an outer wrap that adds surface area contact between the valve and the native aortic annulus to improve valve sealing performance.

On July 10, 2017, the FDA approved an expanded indication for the Medtronic CoreValve, Evolut R and Evolut PRO valves to include patients with intermediate surgical risk for aortic valve replacement.

LOTUS Edge

On November 17, 2020, Boston Scientific announced discontinuation of the LOTUS product due to complexities associated with the product delivery system. The Boston Scientific LOTUS Edge Valve System received FDA premarket approval (P180029) on April 23, 2019. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis (aortic valve area ≤ 1.0 cm^2 or index of ≤ 0.6 cm^2/m^2) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical comorbidities unmeasured by the STS risk calculator). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P180029. (Accessed September 21, 2022)

Portico Transcatheter Aortic Valve Implantation System

The Portico Transcatheter Aortic Valve Implantation System received FDA premarket approval on September 17, 2021. The device is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy

(i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical comorbidities unmeasured by the STS risk calculator). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190023. (Accessed September 21, 2022)

On August 16, 2019, the FDA granted expanded approval for four TAVR devices: CoreValve Evolut R and Evolut PRO (Medtronic), SAPIEN three and SAPIEN three Ultra (Edwards Lifesciences) for the treatment of patients with severe aortic stenosis who are at low risk for surgical aortic valve replacement. The devices are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy. Additional information available at:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021S058
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S085

(Accessed September 21, 2022)

FDA approval status for other brands of aortic valve prostheses, percutaneous delivered can be found on the FDA's Premarket Approval website using Product Code NPT: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed September 21, 2022)

Mitral

The MitraClip Mitral Valve Repair System received FDA premarket approval (P100009) on October 24, 2013. The device is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009. (Accessed September 21, 2022)

A third generation MitraClip device was approved on July 12, 2018.

On March 14, 2019, the FDA approved an expanded indication for the MitraClip NT and MitraClip NTR/XTR Clip Delivery Systems to include secondary MR. The devices, when used with maximally tolerated GDMT, are indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (functional) mitral regurgitation (MR ≥ Grade III per American Society of Echocardiography criteria) in patients with a LVEF ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease. Additional information available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009S028. (Accessed September 21, 2022)

FDA approval status for other brands of mitral valve prostheses, percutaneous delivered can be found on the FDA's Premarket Approval website using Product Code NPU while other mitral valve repair devices can be found using Product Code NKM: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed September 21, 2022)

Pulmonary

Harmony

The Harmony™ TPV System received FDA premarket approval (P200046) on March 26, 2021. The Harmony valve is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% as determined by cardiac MRI) who have a native or surgically-repaired right ventricular outflow tract (RVOT) and are clinically indicated for surgical pulmonary valve replacement. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200046. (Accessed September 21, 2022)

Melody

The Melody Transcatheter Pulmonary Valve (TPV) and the Ensemble Transcatheter Valve Delivery System received FDA premarket approval (P140017) on January 27, 2015. The Melody TPV is indicated for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) dysfunctional RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted; and
- Dysfunctional RVOT conduit with a clinical indication for intervention; and:
  - Regurgitation: ≥ moderate regurgitation; and/or
  - Stenosis: mean RVOT gradient ≥ 35 mmHg

Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140017. (Accessed September 21, 2022)

The Melody TPV and the Ensemble Transcatheter Valve Delivery System were originally approved under Humanitarian Device Exemption (HDE) (H080002) on January 25, 2010. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H080002. (Accessed September 21, 2022)

SAPIEN XT

On February 29, 2016, the FDA granted expanded approval of the Edwards SAPIEN XT Transcatheter Heart Valve to include use in PPVI procedures (P130009). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130009. (Accessed September 21, 2022)

SAPIEN 3

On August 31, 2020, the FDA granted approval of the Edwards SAPIEN 3 Heart Valve System with Edwards Commander Delivery System for use in PPVI procedures (P200015). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200015. (Accessed September 21, 2022)

FDA approval status for other brands of pulmonary valve prostheses, percutaneous delivered can be found on the FDA's Premarket Approval website using Product Code NPV: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed September 21, 2022)

Valve-In-Valve

On March 30, 2015, the FDA approved a second indication for the Medtronic CoreValve System. The device is approved for valve-in-valve replacement and is indicated for use in selected high-surgical risk patients with a degenerated bioprosthetic aortic valve who require another valve replacement procedure.

On October 9, 2015, the FDA granted expanded approval of the SAPIEN XT Transcatheter Heart Valve to include aortic valve-in-valve procedures in high- or extreme-risk candidates to replace a failing bioprosthetic valve.

On June 5, 2017, the FDA granted expanded approval of the SAPIEN 3 valve for aortic and mitral valve-in-valve procedures in high- or extreme-risk candidates to replace a failing bioprosthetic valve.

On February 24, 2017, the FDA granted expanded approval of the Melody Transcatheter Pulmonary Valve (TPV) for pulmonary valve-in-valve procedures to replace a failing bioprosthetic valve.

Cerebral Protection

Sentinel Cerebral Protection System (Claret Medical)

The FDA granted a de novo classification for the Sentinel device on June 1, 2017. Sentinel is indicated to capture and remove thrombus and debris during TAVR procedures in a manner that may prevent embolic material from traveling toward the cerebral circulation. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN160043. (Accessed September 21, 2022)

Additional Products

The following products may not have full FDA approval:

- CardiAQ (Edwards Lifesciences)
- Cardioband™
- Carillon® Mitral Contour System™

- Fortis (Edwards Lifesciences)
- Harpoon
- NeoChord
- Tendyne (Abbott)
- Tiara™ (Neovasc, Inc.)
- TriGUARD 3™ (Keystone Heart) cerebral embolic protection device

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Policy History/Revision Information

Date	Summary of Changes
05/01/2024	**Coverage Rationale** • Revised list of unproven and not medically necessary devices/procedures: o Added "transcatheter superior and inferior vena cava prosthetic valve implantation (CAVI)" o Removed "transcatheter pulmonary heart valve replacement using the Harmony™ valve" ***Aortic*** • Revised notation to indicate requests for transcatheter aortic heart valve replacement for low-flow/low-gradient aortic stenosis *in individuals who do not meet the peak velocity, mean gradient, and valve area criteria listed [in the policy]* will be *considered* on a case-by-case basis; *these requests will be evaluated using recommendations from the American College of Cardiology/American Heart Association Guideline for the Management of Patients With Valvular Heart Disease when all the clinical evaluation has been facilitated by a transcatheter aortic heart valve replacement expert and after appropriate additional testing has been conducted* ***Mitral*** • Added language to indicate: o Transcatheter mitral heart valve repair (e.g., annuloplasty), except where noted [as proven and medically necessary in the policy], is unproven and not medically necessary due to insufficient evidence of efficacy o Transcatheter mitral heart valve reconstruction or replacement is unproven and not medically necessary due to insufficient evidence of efficacy ***Pulmonary*** • Replaced language indicating "transcatheter pulmonary heart valve replacement *using the Melody™ or Sapien valves* is proven and medically necessary when used according to FDA labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract (RVOT) dysfunction with one of the [listed] clinical indications for intervention" with "transcatheter pulmonary heart valve replacement *and related devices (e.g., Alterra)* are proven and medically necessary when used according to FDA labeled indications, contraindications, warnings, and precautions in individuals with right ventricular outflow tract (RVOT) dysfunction with one of the [listed] clinical indications for intervention" **Supporting Information** • Archived previous policy version CS123OH.A

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