UnitedHealthcare Community Plan

Transcatheter Procedures for Heart Valve Conditions (for Ohio Only)

Policy Number: CS123OH.D
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➲ Instructions for Use

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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

Transcatheter aortic heart valve replacement is proven and medically necessary for surgical aortic valve replacement in certain circumstances. 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

Transcatheter edge-to-edge repair of the mitral heart valve is proven and medically necessary under certain circumstances. 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 as addressed in the InterQual criteria 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.

Other Devices and Procedures

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™)
- Transcatheter superior and inferior vena cava prosthetic valve implantation (CAVI)
- Valve-in-valve (ViV) replacement within a failed bioprosthesis for mitral, pulmonary, or tricuspid valves

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
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)

CPT Code	Description
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
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (i.e., caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (i.e., caval valve implantation [CAVI]); open femoral vein approach
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
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. 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 typically has three cusps. When only two cusps are present, the valve is referred to as bicuspid. 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).

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.

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 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 standard for treating tricuspid valve disease is surgical annuloplasty. Devices for transcatheter tricuspid valve repair, reconstruction, and replacement are in development.

Caval valve implantation (CAVI) is an emerging technology for treating TR. In this procedure, a valve is placed in the inferior vena cava alone or in combination with a second valve in the superior vena cava to redirect regurgitant flow away from the tricuspid valve.

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

Ueyama et al. (2021) assessed the impact of aortic valve replacement on survival in individuals with each subclass of low-gradient (LG) aortic stenosis and compared outcomes following SAVR and TAVR. LG, severe aortic stenosis includes a variety of pathophysiology, including classical low-flow, LG (LF-LG), paradoxical LF-LG, and normal-flow, LG (NF-LG) aortic stenosis. The authors performed a pairwise meta-analysis comparing aortic valve replacement versus conservative management and a network meta-analysis comparing SAVR versus TAVR versus conservative management. Thirty-two studies, with a total of 6515 participants and a median follow-up of 24.2 months, were included. The analysis showed that both SAVR and TAVR were associated with significant decreases in all-cause mortality compared with conservative management in all subclasses of LF-LG aortic stenosis. No significant difference was observed between SAVR and TAVR, however all these comparisons were indirect, limiting the confidence in the findings.

In a meta-analysis of seven landmark randomized controlled trials (RCTs), Siontis et al. (2019) compared the safety and efficacy of TAVR versus SAVR across the entire spectrum of surgical risk patients. Across the seven trials, 8020 participants with severe, symptomatic aortic stenosis were enrolled: TAVR (n = 4014) and SAVR (n = 4006). The primary endpoint was all-cause mortality up to two years. The authors reported a lower risk of all-cause mortality (12% relative risk reduction) and stroke (19% relative risk reduction), regardless of underlying surgical risk, up to two years of follow-up. TAVR was linked to a higher risk of permanent pacemaker implantation and major vascular complications, but a reduced risk of major bleeding, new onset atrial fibrillation and acute kidney injury. The following RCTs, previously summarized in this policy, are included in this meta-analysis:

High risk

- PARTNER Cohort A (Smith et al., 2011; Kodali et al., 2012; Mack et al., 2015)
- US CoreValve (Adams et al., 2014; Reardon et al., 2015; Deeb et al., 2016; Gleason et al., 2018)

Intermediate risk

- PARTNER II Cohort A (Leon et al., 2016); [Makkar et al. (2020) reported additional follow-up results after this meta-analysis was published.]

- SURTAVI (Reardon et al., 2017)

Low risk
- Evolut Low Risk (Popma et al., 2019); [Forrest et al. (2022) and Forrest et al. (2023) reported additional follow-up results after this meta-analysis was published.]
- PARTNER 3 (Mack et al., 2019); [Leon et al. (2021) and Mack et al. (2023) reported additional follow-up results after this meta-analysis was published.]

All risk
- NOTION (Thyregod et al., 2015; Søndergaard et al., 2016; Thyregod et al., 2019); [Søndergaard et al. (2019) and Jørgensen et al. (2021) reported additional follow-up results after this meta-analysis was published.]

Using registry data, Ribeiro et al. (2018) evaluated clinical outcomes and changes in LVEF following TAVR in patients with classic LF-LG aortic stenosis. 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 LF-LG aortic stenosis and reduced LVEF. However, approximately one third of patients with LF-LG aortic stenosis 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 LF-LG severe aortic stenosis and reduced LVEF. NCT01835028.

Mitral Valve

Percutaneous Annuloplasty

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of coronary sinus annuloplasty devices for treating mitral regurgitation. Existing studies are limited by large loss to follow-up or lack of relevant comparison group.

D'Amario et al. (2024) performed a systematic review and meta-analysis to compare percutaneous mitral valve repair approaches for treating severe MR. Outcomes of interest were divided into three categories: efficacy, safety and procedural. Clinical efficacy endpoints were all-cause mortality, major adverse cardiovascular events, and post-procedural NYHA functional class < 3. The echocardiographic efficacy endpoint was a post-intervention residual MR less than moderate. Safety and procedural endpoints were also assessed. Two of the eleven observational studies compared MitraClip to Carillon (n = 195), but the authors were not able to draw conclusions due to a lack of robust data.

An ECRI report concluded that Carillon is a safe procedure that may provide clinical benefits in some patients with functional MR; however, the evidence is too limited in quality to support conclusions. The studies reported moderate improvements in physical function and quality of life and modest cardiovascular risk reduction after one year; however, the findings are at high risk of bias from high attrition in the RCT and lack of randomization and small sample or single-center focus in other studies. How Carillon placement compares with medical therapy and other transcatheter mitral valve repair systems is unclear because relevant studies assessed too few patients. Large multicenter RCTs comparing Carillon with conventional mitral repair surgery (in eligible patients), optimal medical therapy (in patients ineligible for surgery), transcatheter edge-to-edge repair, and other transcatheter annuloplasty devices are needed to validate available data and determine Carillon's optimal place in MR treatment (ECRI, 2023a).

Giallauria et al. (2020) performed a meta-analysis of individual patient data from the TITAN, TITAN II, and REDUCE-FMR studies (n = 209). The studies compared transcatheter mitral valve repair with the Carillon device to optimal medical therapy alone in patients with functional MR. Measured outcomes included MR severity/grade, left ventricular remodeling, functional status, and heart failure-related outcomes in heart failure patients with reduced ejection fraction. At one-year follow-up, the authors reported that the Carillon device was more effective than optimal medical therapy alone for improving MR grade in patients with functional MR; however, left ventricular ejection fraction improvement did not differ significantly between the two groups. NYHA functional status improved more with Carillon than with medical therapy alone. Heart failure-related hospitalizations occurred less frequently among Carillon recipients than among control group patients. Two of the three trials were small and lacked randomization and control; the third was randomized but had high patient attrition. Furthermore, Carillion was not compared to other proven transcatheter or surgical approaches to MR. The study by Siminiak et al. (2012) previously discussed in this policy was included in this meta-analysis.

In the REDUCE FMR trial, Witte et al. (2019) evaluated the effects of the Carillon device on MR severity and left ventricular remodeling. In this blinded, randomized, proof-of-concept, sham-controlled trial, patients receiving optimal heart failure medical therapy were assigned to a coronary sinus-based mitral annular reduction approach for functional

MR or sham. The primary endpoint was change in mitral regurgitant volume at 12 months, measured by echocardiography. Patients (n = 120) were randomized to either the treatment (n = 87) or the sham-controlled (n = 33) arm. There were no significant differences in baseline characteristics between the groups. In the treatment group, 73 of 87 (84%) had the device implanted. The primary endpoint was met with a statistically significant reduction in mitral regurgitant volume in the treatment group compared to the control group. Additionally, there was a significant reduction in left ventricular volumes in patients receiving the device versus those in the control group. This study was not powered to evaluate clinical endpoints. Carillion was not compared to other proven transcatheter or surgical approaches to MR. Studies are underway to assess the effect of this approach on mortality and hospitalization in patients with FMR. NCT02325830.

Schofer et al. (2009) evaluated patients with moderate heart disease who were enrolled in the Carillon Mitral Annuloplasty Device European Union Study (AMADEUS). Percutaneous mitral annuloplasty was achieved through the coronary sinus with the Carillon Mitral Contour System. Of the 48 patients enrolled in the trial, 30 received the Carillon device. Eighteen patients did not receive a device because of access issues, insufficient acute FMR reduction, or coronary artery compromise. Echocardiographic FMR grade, exercise tolerance, NYHA class, and quality of life were assessed at baseline and 1 and 6 months. The major adverse event rate was 13% at 30 days. At 6 months, the degree of FMR reduction among 5 different quantitative echocardiographic measures ranged from 22% to 32%. Six-minute walk distance improved from 307+/-87 m at baseline to 403+/-137 m at 6 months. Quality of life, measured by the Kansas City Cardiomyopathy Questionnaire, improved from 47+/-16 points at baseline to 69+/-15 points at 6 months. The authors concluded that percutaneous reduction in FMR with a novel coronary sinus-based mitral annuloplasty device is feasible in patients with heart failure, is associated with a low rate of major adverse events and is associated with improvement in quality of life and exercise tolerance. Study limitations include the lack of a randomized, blinded control group with whom to compare safety and efficacy results.

Other Minimally Invasive Mitral Valve Repair Devices

Several other minimally invasive mitral valve repair devices are in the early stages of development. Large, prospective studies with long-term follow-up are needed to establish their clinical role.

Small case series from a single research group reported early results with the Harpoon expanded polytetrafluoroethylene (ePTFE) chordal implantation system. The results were promising; however, larger prospective studies with long-term follow-up are needed to establish their clinical role (Gammie et al., 2021; Gammie et al., 2016; Gammie et al., 2018).

Messika-Zeitoun et al. (2019) reported the 1-year outcomes of 60 consecutive patients with moderate or severe secondary MR who underwent the Cardioband procedure. At 1 year, most patients had moderate or less MR and experienced significant functional improvements. There were two in-hospital deaths (no device-related), one stroke, two coronary artery complications and one tamponade. Anchor disengagement, observed in 10 patients, resulted in device inefficacy in five patients and led to device modification halfway through the study to mitigate this issue. Study limitations include lack of randomization and control and short-term follow-up.

Colli et al. (2018) reported early results of the NeoChord mitral valve repair system for treating degenerative MR. In a consecutive case series of patients, 213 participants were enrolled in the NeoChord Independent International Registry. All participants presented with severe MR. The primary end points were procedural success, freedom from mortality, stroke, reintervention, recurrence of severe MR, rehospitalization and decrease of at least 1 NYHA functional class at 1-year follow-up. Procedural success was achieved in 206 (96.7%) patients. At 1-year follow-up, overall survival was 98 ±1%. Composite end point was achieved in 84 ±2.5% for the overall population. Study limitations include lack of randomization and control and short-term follow-up.

Pulmonary Valve

Dimas et al. (2024) reported 2-year outcomes of the main cohort of the Alterra prospective, single-arm, multicenter pivotal trial using the 29 mm SAPIEN 3 transcatheter heart valve. The system was evaluated in patients with moderate or greater pulmonary valve regurgitation. The primary endpoint was valve dysfunction at six months, defined as a composite of RVOT/pulmonary valve reintervention, moderate or greater total pulmonary regurgitation, and mean RVOT/pulmonary valve gradient 35 mm Hg or greater. Of 97 individuals screened, 60 underwent implantation. No participants had valve dysfunction at six months. At two years, the majority of patients (92.5%) had mild or less PR, with no reports of coronary compression, stent fractures warranting reintervention, or endocarditis. Of the 21 patients (34.4%) who experienced early (days 0-1) arrhythmias, 12 had episodes of nonsustained ventricular tachycardia that resolved with medication. One individual underwent reintervention secondary to an iatrogenic RVOT obstruction. There were no deaths or explantations through two years.

Gillespie et al. (2023) presented one-year outcomes in a pooled cohort of clinical trial participants from three earlier studies of the Harmony transcatheter pulmonary heart valve. The Harmony device continued to demonstrate favorable clinical and hemodynamic outcomes across studies and valve types through one year. Continued follow-up of this patient cohort through 10 years will allow long-term evaluation of valve performance and durability.

In the prospective, single-arm, multicenter COMPASSION S3 study (n = 58), Lim et al. (2023) evaluated the safety and effectiveness of the SAPIEN 3 transcatheter heart valve for treating patients with a dysfunctional RVOT conduit or surgical valve in the pulmonary position. The primary end point was a composite of valve dysfunction at one year comprising RVOT reintervention, ≥ moderate total pulmonary regurgitation, and mean RVOT gradient > 40 mm Hg. Prestenting was performed 53% of the time. At discharge, the device success was 98%. At 30 days, there were no major adverse clinical events. At one year, the composite primary end point of valve dysfunction occurred in 4.3% of participants. No mortality, endocarditis, thrombosis, or stent fractures were reported at one year. Long-term follow-up to determine the durability of these results will continue.

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; updated 2024).

McElhinney et al. (2022) evaluated mid- and long-term outcomes after transcatheter pulmonary valve replacement in a large, multicenter cohort using international registry data on 2476 patients. The analysis found that survival and freedom from reintervention or surgery after transcatheter pulmonary valve replacement are generally comparable to outcomes of surgical conduit/valve replacement across a wide range of patient ages.

Ribeiro et al. (2020) performed a systematic review and meta-analysis of 18 studies comparing transcatheter with surgical pulmonary valve replacement. The primary endpoint was early mortality after replacement. Secondary endpoints included procedure-related complications, length of hospital stay, mortality during follow-up, infective endocarditis, need for reintervention, post-replacement transpulmonary peak systolic gradient, and significant pulmonary regurgitation. No significant difference was observed in the primary endpoint of early mortality between the groups. At midterm follow-up the transcatheter technique was comparable with the surgical procedure in terms of repeat intervention but was associated with an increased risk of infective endocarditis. In selected patients, the transcatheter technique was found to have a shorter length of hospital stay and fewer procedure-related complications.

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.

Kenny et al. (2018) reported 3-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 3-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 3 years, with low rates of all-cause mortality, reintervention and endocarditis and no stent fractures.

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). Note: These versions of the SAPIEN valve are no longer commercialized.

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 TR. 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.

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 +/- .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.

Tricuspid Valve

An ECRI report 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, 2022c).

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).

Transcatheter Tricuspid Valve Replacement (TTVR)

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of TTVR for treating tricuspid valve disease. Data from one RCT shows promising results with improvements in functional status and quality of life, but early (< 3 months) mortality and severe bleeding are concerning. Longer follow-up is needed to assess whether these early unfavorable findings are compensated with later favorable results. Furthermore, confidence in findings of this RCT is limited by the open-label design. Other publications are limited by single-arm and observational design.

The TRISCEND II international, multicenter randomized pivotal trial evaluated the EVOQUE TTVR in participants with severe, symptomatic TR (Hahn et al., 2024). The trial used a **two-phase** design, based on the FDA Breakthrough Device Designation program. Investigators evaluated 30-day safety and 6-month effectiveness end points for the first 150 participants in the initial phase and a 1-year safety and effectiveness end point for the full cohort of 400 participants in the second phase. Participants were predominantly elderly (mean age 79.2 years), with a high prevalence of comorbidities. Study limitations include open-label design, reliance on patient-reported outcomes and short-term follow-up.

- In **phase one**, the first 150 participants were randomized to TTVR with optimal medical therapy (n = 96) or medical therapy alone (n = 54). Early data from phase one showed a major adverse event rate of 27.4 percent at 30 days and significant reductions in TR, with 98.8 percent of participants achieving ≤ moderate TR and 93.8 percent achieving ≤ mild TR at six months. Additionally, there were improvements in quality of life and functional outcomes at six months for the composite endpoint including improvements in the Kansas City Cardiomyopathy Questionnaire overall summary (KCCQ-OS) score, NYHA functional class and six-minute walk distance.
- In **phase two** of the full cohort, 400 participants were randomized in a 2:1 ratio to undergo either TTVR with medical therapy (n = 267) or medical therapy alone (n = 133). The primary endpoint was a hierarchical composite outcome, including death from any cause, need for a right ventricular assist device or heart transplantation, additional tricuspid valve interventions, hospitalization for heart failure, improvement of ≥ 10 points on the KCCQ-OS, improvement of at least one NYHA functional class, and a ≥ 30 meter improvement on the six-minute walk test. At one year, TTVR was associated with a slightly lower mortality rate (12.6%) compared to the control group (15.2%). TTVR recipients experienced a lower hospitalization rate for heart failure (20.9%) compared to the control group (26.1%). Improvement in KCCQ-OS scores by at least 10 points was achieved in 66.4% of TTVR recipients versus 36.5% in the control group. TTVR recipients showed marked improvement in NYHA class, with 78.9% achieving at least one functional class improvement, compared to 24.0% in the control group. Improvement in the six-minute walk test was observed in 47.6% of TTVR recipients compared to 31.8% in the control group. Additionally, TTVR significantly reduced TR severity, with 95.3% of participants achieving mild or less TR at 1 year, compared to only 16.1% in the control group. TTVR adverse events included severe bleeding in 15.4% of participants versus 5.3% in the control group, and new permanent pacemaker implantation in 17.4% of participants compared to 2.3% of controls.

A Hayes report found minimal support for the use of the EVOQUE Tricuspid Valve Replacement System to treat individuals with severe (or greater) TR despite optimal medical therapy who are not candidates for transcatheter repair or open-heart surgery and have a poor prognosis. Longer-term follow-up data is expected from ongoing studies. Higher quality RCTs comparing EVOQUE with other replacement valve options are needed (Hayes, 2024).

The prospective, single-arm, multicenter TRISCEND registry enrolled 176 patients to evaluate the safety and performance of the EVOQUE TTVR in individuals with ≥ moderate, symptomatic TR despite medical therapy. The study population was moderately high risk; mean age was 79 years, 71% were female, 88.0% had at least severe TR, 75.4% had NYHA class III-IV symptoms, and 40.9% had a prior heart failure hospitalization within the preceding year. At one year, the elderly, highly comorbid population experienced improved clinical, functional, and quality-of-life outcomes, with low mortality and reduced hospitalization rates. TR was reduced to ≤ mild in 97.6%, with significant increases in stroke volume and cardiac output. NYHA class I or II was achieved in 93.3%. KCCQ score increased by 25.7 points, and the six-minute walk distance increased by 56.2 meters. All-cause mortality was low at 9.1%, and 10.2% of patients were hospitalized for heart failure. The primary limitation of this study is the single-arm design without comparison to standard of care. Additionally, these results reflect the treatment of a highly selected patient cohort in specialized centers with extensive experience in transcatheter valve intervention, and outcomes may not be generalizable to less experienced centers (Kodali et al., 2023). This study is included in the Hayes report cited above.

An ECRI report on the safety and effectiveness of TTVR for treating TR found the evidence was inconclusive. RCTs reporting on clinical outcomes and comparing TTVR with medical treatment, transcatheter tricuspid valve repair, and prosthetic valves from different manufacturers are needed to address evidence gaps (ECRI, 2022b).

Buğan 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 failed to show 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 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.

In an early, compassionate use study, the EVOQUE TTVR system demonstrated durable efficacy, persistent improvement in symptom status, and low rates of mortality and heart failure hospitalizations at one year in a high-risk population. All 27 patients had clinical right-sided heart failure and were deemed inoperable and unsuitable for transcatheter edge-to-edge repair by the institutional heart teams. At one year, mortality was 7%, 70% of patients were NYHA functional class I/II, and 96% and 87% of patients had a TR grade ≤ 2+ and ≤ 1+, respectively. While the results are promising, the authors noted that further larger-scale randomized trials with a control arm to validate clinical efficacy and better define optimal patient selection are needed. Study limitations include the observational design, lack of a control group and small sample size. Additionally, these results reflect treatment in specialized centers with extensive experience in transcatheter valve intervention, and outcomes may not be generalizable to less experienced centers (Webb et al., 2022). This study is included in the Hayes report cited above.

Transcatheter Edge-to-Edge Tricuspid Valve Leaflet Repair

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of transcatheter edge-to-edge tricuspid valve leaflet repair. One RCT failed to demonstrate benefit on mortality, hospitalizations, and functional status. While the findings of this RCT are promising for improvement in quality of life, confidence in these findings is limited by the lack of participants' masking to assignment and social desirability. Other publications are limited by single-arm design.

Rehan et al. (2024) performed a systematic review and meta-analysis to assess echocardiographic parameters and clinical outcomes in patients undergoing tricuspid transcatheter edge-to-edge repair (T-TEER) for moderate to severe (grade III-V) isolated TR. One RCT and 14 observational studies were included. GRADE assessment was performed and studies were assessed for risk of bias and publication bias. The authors reported promising results in terms of TR grade and volume, NYHA class, and six-minute walking distance. T-TEER procedural success was 97%. No significant differences in LVEF, fractional area change, or tricuspid annular plane systolic excursion were observed. Most of the studies in this review were single-arm prospective observational studies or retrospective analyses with moderate sample sizes and lacking a control group and randomization. This publication's data analyses are limited to pre/post comparison without comparison to a concurrent group undergoing a different intervention. Further large scale RCTs comparing the efficacy of T-TEER with traditional therapeutic strategies are needed to establish T-TEER as a first-line treatment option for patients with TR. (Sorajja et al. 2023 and Lurz et al., 2021, summarized below, are included in this systematic review.)

An ECRI report on the TriClip device for treating TR in patients at intermediate to high risk for tricuspid valve surgery concluded that TriClip is safe and improves quality of life and functional status more than best-available medical therapy alone at up to two-year follow-up in patients with moderate or higher grade TR. While ECRI deemed the evidence favorable, the report also notes the studies report too few events and too short follow-up to enable conclusions about whether TriClip reduces mortality rates compared with best-available medical therapy. Additional studies are needed to validate findings. T-TEER with TriClip presents a treatment option for patients with symptomatic TR whose symptoms persist despite best-available medical care. Ongoing clinical trials may validate the findings and address evidence gaps (ECRI, 2024).

The TRILUMINATE single-arm study was an international, prospective, multicenter study designed to evaluate the safety and effectiveness of the TriClip T-TEER system in patients with symptomatic moderate or greater TR who were at high risk for surgery and had valve anatomies suitable for T-TEER. Of 97 individuals who met the inclusion criteria, the first 85 were enrolled and underwent successful TriClip implantation. The primary safety endpoint was a composite of major adverse events at six months. The primary efficacy endpoint was a reduction in TR severity by at least one grade at 30 days. Clinical status was assessed using NYHA functional class, the KCCQ score, and the six-minute walk test. At six months, Nickenig et al. (2019) reported that both primary endpoints were met. The procedure effectively reduced TR and significantly improved clinical symptoms and exercise capacity. The study also showed that reduction in TR with the

TriClip device was associated with significant right heart remodeling and improved right ventricular function; however, it was unclear that a reduction of TR was associated with reduced morbidity and mortality. T-TEER using the TriClip implant was found to be safe and effective, with sustained benefits at one, two and three years (Lurz et al., 2021; vonBardelben et al., 2023; Nickenig et al., 2024). This study was limited by lack of randomization and control and small sample size.

The prospective, open-label, randomized TRILUMINATE pivotal trial evaluated the safety and effectiveness of T-TEER in symptomatic participants with severe TR. A total of 350 participants were randomly assigned in a 1:1 ratio to receive either T-TEER with the TriClip device (n = 175) or medical therapy alone (n = 175). The primary end point was a hierarchical composite that included death from any cause or tricuspid valve surgery, heart failure hospitalization and improved quality of life as measured with the KCCQ at one year. The secondary end points were freedom from major adverse events within 30 days (T-TEER group only), a change from baseline in the KCCQ score at the one-year follow-up, a reduction in TR severity to moderate or less by the 30-day follow-up, and a change from baseline in the six-minute walk distance at the one-year follow-up. The mean participant age was 78 years, and 54.9% were women. Results showed that T-TEER was safe (only 3 major adverse events occurred within 30 days) and effectively reduced TR severity (TR grade ≤ 2+ at 30 days was present in 87.0% of the T-TEER group versus 4.8% of the control group). However, the incidence of death or tricuspid valve surgery and the rate of hospitalization for heart failure did not appear to differ between the groups. The difference in the primary outcome was driven by a significantly greater increase in the KCCQ score from baseline to follow-up in T-TEER-assigned group (mean improvement 12.3 versus 0.6 points), which could have been biased by lack of participant masking. NYHA class was also improved with T-TEER, although the difference in six-minute walk distance from baseline to follow-up was not significantly different between groups (Sorajja et al., 2023). NCT03904147.

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, RCTs are needed to confirm these findings.

Caval Valve Implantation (CAVI)

There is insufficient quality evidence in the clinical literature demonstrating the long-term safety and efficacy of CAVI for treating tricuspid valve disease. Identified publications are limited by short-term follow up, open-label design, and small sample sizes.

Badwan et al. (2023) performed a meta-analysis of studies evaluating clinical outcomes after caval valve implantation (CAVI) for severe symptomatic tricuspid regurgitation. Fifteen studies (n = 142) were included, 8 of which were case reports or case series. The median follow-up duration ranged from 61 to 350 days. The authors found that CAVI was associated with a high procedural success rate and significant reductions in NYHA functional class and TR severity but noted several limitations, including small sample size, short-term follow-up, and dissimilar definitions of procedural success. Also, multiple CAVI systems are incorporated into the pooled analysis. While hemodynamic and functional improvements are encouraging, larger-scale prospective studies with longer follow-up are needed.

In the TRICAVAL prospective, open-label, single-center, randomized trial, Dreger et al. (2020) compared the impact of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) on exercise capacity with optimal medical therapy in patients with severe TR and high surgical risk. Twenty-eight patients were randomized to optimal medical therapy (n = 14) or CAVI (n = 14). The primary endpoint was maximal oxygen uptake at three months. Secondary endpoints included the six-minute walk test, NYHA functional class, NT-proBNP levels, right heart function, unscheduled heart failure hospitalization, and quality of life. Patients underwent follow-up examinations one, three, six, and twelve months after randomization. Maximal oxygen uptake did not change significantly in either group after three months and there was no difference between the medical therapy and CAVI groups. Compared to baseline, CAVI improved NYHA class, dyspnea, and quality of life after three months. However, there were no statistically significant differences in the secondary endpoints between the groups. CAVI did not result in a superior functional outcome compared to medical therapy. Due to an unexpectedly high rate of valve dislocations, the study was stopped for safety reasons resulting in a low number of enrolled patients. The study may have been underpowered to detect clinically significant differences between groups.

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. Identified evidence is limited by the observational design of the studies. The evidence for these procedures is still evolving and findings are promising for aortic, pulmonary, and mitral valves.

Aortic

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.

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.

Mitral

Ismayl et al. (2023) conducted a systematic review and meta-analysis of observational studies comparing ViV TMVR versus redo surgical mitral valve replacement in a degenerated bioprosthetic mitral valve. Outcomes included in-hospital, 30-day, 1-year, and 2-year mortality, stroke, bleeding, acute kidney injury, arrhythmias, permanent pacemaker insertion, and hospital length of stay. A total of six observational studies (n = 707) were included. ViV TMVR was associated with better outcomes than redo surgical mitral valve replacement, including lower complication rates and shorter hospital length of stay, with no significant difference in mortality rates. The findings are limited by the observational nature of the included studies, which could have led to biased estimates. Large-scale randomized trials are needed to confirm these findings.

A single-center, retrospective cohort study by Taha et al. (2022) was performed to evaluate the feasibility and safety of TMVR in patients with high surgical risk with degenerated mitral bioprostheses (TMViV), failed surgical rings (TMViR), and mitral annular calcification (TMViMAC). Patients with high surgical risk who underwent TMVR from February 2017 to September 2020, were enrolled in this study. The TMVR procedure was performed using Edwards SAPIEN 3 valves through the transseptal approach. Sixty-four patients aged 62.7 ±16.1 years with an STS score of 9.2 ±3.7% underwent TMVR [35 (55%) TMViV, 16 (25%) TMViR, and 13 (20%) TMViMAC]. Mitral stenosis was more frequent in TMViV, mitral regurgitation was more frequent in TMViR, and combined mitral stenosis and regurgitation were more frequent in TMViMAC ($p < 0.05$). The MV gradient was 14.3 ±5.3 mmHg and the MV area was 1.5 ±0.6 cm^2. The 29 mm valve was frequently used in TMViV and TMViMAC, while the 23 mm valve was frequently used in TMViR ($p = 0.003$). The procedural and fluoroscopy times were 58.7 ±8.9 and 41.1 ±8.2 minutes, respectively. Technical success was reported in 62 (98.4%) patients; one TMViR patient experienced valve embolization and salvage surgery, and one TMViMAC patient experienced slight valve malposition. At three months, two (3.1%) patients showed valve thrombosis (treated with anticoagulation), and one (1.6%) patient developed a paravalvular leak (underwent surgical MV replacement). At six months, three (4.7%) patients showed valve degeneration (underwent surgical MV replacement). Throughout follow-up, no patient exhibited mortality. The authors concluded that TMVR is a feasible and safe approach in patients with high surgical risk. TMViV and TMViR are reasonable as the first treatment approaches, and TMViMAC seems encouraging. Limitations include lack of comparison with other therapeutic approaches, small sample size (n = 64), short duration of follow-up (six months), and single-center design. Further research is needed to determine the clinical relevance of these findings.

Eleid et al. (2021) conducted a systematic review of observational studies to evaluate outcomes after transcatheter mitral valve-in-valve ViV implantation for treatment of a degenerated mitral bioprostheses. Five studies (n = 2684) were included in the review. Procedural technical success ranged from 94-98%, with 1-3% rates of periprocedural death, 0-2% stroke and 1-5% risk of left ventricular outflow tract (LVOT) obstruction. Thirty-day post-procedure mean mitral prosthetic gradient ranged from 6-7 mmHg and residual mitral regurgitation was mild or less in 96-100% of patients. Thirty-day survival and one-year survival ranged from 93-97% and 83-89% respectively. Further longitudinal studies are needed to assess long-term outcomes. The findings are limited by lack of comparison groups.

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 mmHg. 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.

Cerebral Protection

There is insufficient quality evidence in the clinical literature demonstrating the efficacy of transcatheter cerebral protection devices in improving stroke, neurological, and cognitive outcomes following TAVR. A large RCT failed to show a benefit on stroke. Combined observational and randomized studies meta-analyses suggest benefit, but observational studies could be subject to biases.

A prospective, post-market, multi-center, RCT 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. (2020) 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, 2017; updated 2022).

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 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 RCTs (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 RCTs 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.

In patients with BAV and symptomatic, severe aortic stenosis, TAVR 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 TAVR 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. See 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 a joint guideline for the management of valvular heart disease, the ESC and the EACTS (Vahanian et al., 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.

The guideline recommends SAVR in younger patients who are at low risk for surgery (< 75 years and STS PROM/ EuroSCORE II < 4%) or in patients who are operable and unsuitable for transfemoral TAVI. TAVI is recommended in 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.

Mitral

Clinical data is limited on transcatheter mitral valve repair systems other than TEER, as well as transcatheter mitral valve replacement devices.

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.

ViV

Transcatheter, transfemoral valve-in-valve implantation in the aortic position should be considered by the heart team depending on anatomic considerations, features of the prosthesis, and in patients who are at high operative risk or inoperable.

Transcatheter valve-in-valve implantation in the mitral and tricuspid position has a IIb recommendation which indicates the procedure may be considered in selected patients at high-risk for surgical reintervention. 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 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, 2021b).

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).

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

FDA approval status for transcatheter aortic valve prostheses can be found by searching the FDA's Premarket Approval (PMA) database using Product Code NPT: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021.
- Evolut™ FX (Medtronic)
- Evolut™ PRO (Medtronic)
- Evolut™ R (Medtronic)

(Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190023.
- Navitor™ (Abbott)

(Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031.
- SAPIEN 3 Ultra RESILIA (Edwards Lifesciences)
- SAPIEN 3 Ultra (Edwards Lifesciences)
- SAPIEN 3 (Edwards Lifesciences)

(Accessed December 18, 2024)

Mitral

FDA approval status for transcatheter mitral valve repair devices can be found by searching the FDA's Premarket Approval (PMA) database using Product Code NKM: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100009.
- MitraClip™ (Abbott)

(Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P220003.
- PASCAL (Edwards Lifesciences)

(Accessed December 18, 2024)

Pulmonary

FDA approval status for transcatheter pulmonary valve prostheses and related devices can be found by searching the FDA's Premarket Approval (PMA) database using Product Code NPV: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. (Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200046.
- Harmony™ (Medtronic)

(Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140017.
- Melody™ (Medtronic)

(Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200015.
- SAPIEN 3 (Edwards Lifesciences)
- SAPIEN 3 with Alterra Adaptive Prestent (Edwards Lifesciences)

(Accessed December 18, 2024)

Tricuspid

FDA approval status for transcatheter tricuspid valve prostheses can be found by searching the FDA's Premarket Approval (PMA) database using Product Code NPW: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230013.
- EVOQUE (Edwards Lifesciences)

(Accessed December 18, 2024)

FDA approval status for transcatheter tricuspid valve repair devices can be found by searching the FDA's Premarket Approval (PMA) database using Product Code NPS: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed December 18, 2024)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230007.
- TriClip™ (Abbott)

(Accessed December 18, 2024)

Cerebral Protection

FDA approval status for cerebral embolic protection devices used during transcatheter intracardiac procedures can be found by searching the FDA's De Novo or 510(k) Premarket Notification database using Product Code PUM: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm or https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
- SENTINEL™ (Boston Scientific)

(Accessed December 18, 2024)

Additional Products

The following products may not have full FDA approval:
- Cardioband™
- Carillon® Mitral Contour System™
- Harpoon
- Intrepid™ (Medtronic)
- NeoChord
- Tendyne™ (Abbott)
- Tiara™ (Neovasc, Inc.)
- TricValve®
- TriGUARD 3™ (Keystone Heart)

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Policy History/Revision Information

Date	Summary of Changes
07/01/2025	**Title Change** • Previously titled *Transcatheter Heart Valve Procedures (for Ohio Only)* **Coverage Rationale** ***Aortic*** • Added language to indicate transcatheter aortic heart valve replacement is proven and medically necessary for surgical aortic valve replacement in certain circumstances ***Mitral*** • Added language to indicate transcatheter edge-to-edge repair of the mitral heart valve is proven and medically necessary in certain circumstances • Replaced language indicating "transcatheter mitral heart valve repair (e.g., annuloplasty), except *where noted [in the policy as proven]*, is unproven and not medically necessary" with "transcatheter mitral heart valve repair (e.g., annuloplasty), except *as addressed in the InterQual® criteria [referenced in the policy]*, is unproven and not medically necessary" **Applicable Codes** • Added CPT codes 0805T and 0806T • Removed CPT code 33999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS123OH.C

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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