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Medical Policy

Subject:	Transcatheter Heart Valve Procedures		
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Description/Scope

This document addresses the transcatheter (percutaneous or catheter-based) approach for aortic or pulmonary heart valve replacement, transcatheter mitral valve repair using leaflet repair or percutaneous annuloplasty, and transcatheter tricuspid valve repair or replacement.

Position Statement

Medically Necessary:

Transcatheter Aortic Valve Replacement (TAVR):

TAVR using a U.S Food and Drug Administration (FDA) approved device* is considered **medically necessary** when ~~**all**~~ the following criteria have been met:

A. The individual has severe degenerative, native valve aortic stenosis demonstrated by **one** of the following:
   1. the AVA is equal to or less than 0.8 cm^2; **or**
   2. the AVA index is equal to or less than 0.5 cm^2/m^2; **or**
   3. either a mean aortic valve gradient of more than 40 mm Hg; **or**
   4. a peak aortic-jet velocity of more than 4.0 m/sec; **and**

B. Heart failure symptoms of New York Heart Association (NYHA) class II or greater; **and**

C. The individual is in **one** of the following categories:
   1. **Low open surgical risk** and 80 years of age or older; **or**
   ~~C.~~2. **Intermediate or greater open surgical risk** ~~The individual is at intermediate or greater risk for open surgical therapy~~ (~~that is,~~ predicted risk of surgical mortality at 30 days greater than or equal to 3% ~~at 30 days~~) as determined by at least two physicians.

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Valve-in-valve TAVR implantation using an FDA approved device* is considered **medically necessary** for treatment when the following criteria are met:

A. The individual has failure (that is, stenosed, insufficient, or both) of previous open surgical bioprosthetic *aortic* valve; **and**
B. The individual is at high or greater risk for open surgical therapy (that is, Society of Thoracic Surgeons operative risk score greater than or equal to 8% or at a 15% or greater risk of operative mortality at 30 days) as determined by at least two physicians.

***Note:** Please refer to background section of document for list of FDA approved transcatheter heart valve (THV) devices used for TAVR

Transcatheter Pulmonary Valve (TPV):

TPV implantation with a FDA approved device** is considered **medically necessary** when the following criteria are met:

A. Existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted; **and**
B. Dysfunctional RVOT conduits with one of the following clinical indications for intervention:
   1. moderate or greater pulmonic regurgitation; **or**
   2. pulmonic stenosis with a mean RVOT gradient greater or equal to 35 mm Hg.

****Note:** Please refer to background section of document for list of FDA approved TPVs

Not Medically Necessary:

Transcatheter (aortic, pulmonic, or valve-in-valve) valve replacement is considered **not medically necessary** when the criteria above are not met.

Investigational and Not Medically Necessary:

Transcatheter mitral valve repair using leaflet repair (for example, MitraClip Clip Delivery System) is considered **investigational and not medically necessary** for all indications.

Valve-in-valve transcatheter mitral valve repair is considered **investigational and not medically necessary** for all indications.

Transcatheter mitral valve repair using percutaneous annuloplasty (for example, CARILLON Mitral Contour System) is considered **investigational and not medically necessary** for all indications.

Transcatheter tricuspid valve repair or replacement is considered **investigational and not medically necessary** for all indications.

Rationale

TAVR:

According to the 2008 update of the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the management of individuals with valvular heart disease, the society made a Class I recommendation for conventional surgical aortic valve replacement (AVR) in symptomatic individuals with severe aortic stenosis (AS) (Bonow, 2008). Aortic valve replacement is also recommended in certain circumstances for individuals with severe stenosis who are asymptomatic, and for individuals with mild to moderate stenosis undergoing coronary artery bypass graft (CABG) when there is evidence that progression may be rapid.

A multicenter case series evaluated the outcomes of 345 TAVR (also known as transcatheter aortic valve implantation) procedures (transfemoral [TF]: 168; transapical [TA]: 177) in 339 participants, who presented with severe symptomatic AS at very high or prohibitive surgical risk (Rodés-Cabau, 2010). Outcome results were reported in 332 cases, 30-day procedural success rate (93.3%) and 10.4% mortality (TF: 9.5%, TA: 11.3%). A survival rate of 76% was reported at 1 year follow-up, with the majority of deaths resulting from non-cardiac conditions. The authors concluded the need for further evaluation; the PARTNER (Placement of AoRTic traNscatheterER valves) clinical trial will provide needed randomized comparison of TAVR with normal therapy.

Leon and colleagues (2010), reported on the ongoing PARTNER clinical trial. This multicenter study evaluated the safety and effectiveness of Edwards SAPIEN THV via TF delivery, in a stratified population of inoperable subjects (called the Cohort B study). The inoperable candidates with severe symptomatic AS in Cohort B were randomized to treatment with TF TAVR or control with standard therapy (including balloon aortic valvuloplasty) with 179 in each group; clinical outcomes were evaluated at 30 days and 1 year (median follow-up 1.6 years). Investigators

determined each candidate's vascular access for TF delivery; individuals who failed to meet the criteria for TF delivery were not enrolled. In the TAVR group, 173 individuals underwent the procedure receiving heparin during the TAVR and dual antiplatelet therapy (aspirin and clopidogrel) regimen for 6 months post procedure. Other study enrollment eligibility included a functional NYHA class II or greater. Severe symptomatic AS was defined by aortic-valve area of less than 0.8 cm^2, a mean aortic-valve gradient of 40 mm Hg or more, or a peak aortic-jet velocity of 4.0 m per second or more. Additionally, at least two cardiovascular surgeon investigators had to agree that the individual was not a suitable candidate for surgery due to coexisting conditions that would be associated with a predicted probability of 50% or more of either death by 30 days after surgery or a serious irreversible condition. Study *exclusion criteria* for Cohort B included: a bicuspid or noncalcified aortic valve, acute myocardial infarction, a left ventricular ejection fraction of less than 20%, a significant abdominal or thoracic aortic disease including aneurysm, a transient ischemic attack or stroke within the previous 6 months, hypertrophic cardiomyopathy with or without obstruction, blood dyscrasias, echocardiographic evidence of intra-cardiac mass, thrombus or vegetation, severe renal insufficiency and life expectancy of less than 12 months due to non-cardiac co-morbid conditions. Researchers categorized the overall population at high risk (Society of Thoracic Surgeons (STS) score, 11 ± 6%) including both study groups, although there were individuals with low STS scores who had pre-existing conditions that contributed to the surgeon's rationale for deeming a participant ineligible for surgery. In the TAVR group there were 11 (6.4%) reported deaths in the initial 30 days after the procedure. The author identified limitations in the study as evidenced by the protocol-mandated selection criteria with relevant individual subgroups: individuals in need of treatment for coronary stenosis and severe peripheral vascular disease. Additional concerns with the study relate to the equivalence and management of the control group. The control and treatment groups differed in several domains such as presence of atrial fibrillation and extensive aortic calcification, which might indicate the presence of confounders not equalized by the randomization. In addition, some, but not all, of the control group underwent balloon valvuloplasty (83.8%), although the natural history of the AS was unchanged and some even had aortic valve surgery regardless of their initial inoperable classification. The mortality in this control arm exceeded that expected for an untreated population which raises the concern that this group may not have been an appropriate control or that the treatment they received was somehow harmful. In summary, the authors emphasized the need for other randomized trials instead comparing aortic-valve replacement with TAVR in high-risk individuals with AS who are viable surgical candidates, as well as in the low-risk population.

A multicenter study by Smith and colleagues (2011) compared transcatheter versus surgical aortic valve replacement (SAVR) in high-risk individuals with AS. A total of 699 individuals were randomized to receive the TAVR or surgical replacement with the primary end point of death from any cause at 1 year. The 30-day mortality rate was 3.4% for the TAVR group and 6.5% for the surgical group (p=0.07) and at 1 year 24.2% and 26.8% (p=0.44). The rate of periprocedural risks such as major bleeding and new onset atrial fibrillation were significantly

higher in the surgical population. The incidence of major stroke reported for the TAVR group was 3.8% and 2.1% in the surgical group at 30 days; at 1 year 5.1% and 2.4% (p=0.07). Also at 30 days, more major vascular complications were reported in the TAVR (11.0%) group than in the surgical group (3.2%) (p<0.001). The authors concluded "in high-risk patients with severe AS, transcatheter and surgical procedures for aortic-valve replacement were associated with a similar rate of survival at 1 year, although there were important differences in periprocedural risk."

A health-related quality of life study (Reynolds, 2011) evaluated participants after TAVR in inoperable individuals with severe AS. The quality of life assessments were performed at baseline, 1, 6 and 12 months using the 12-item Short Form-12 General Health Survey (SF-12) and Kansas City Cardiomyopathy Questionnaire (KCCQ) (range, 0-100; higher = better). The PARTNER clinical trial evaluated the Edwards SAPIEN valve in individuals with calcific AS who are considered high-risk for conventional open-heart valve surgery. The KCCQ summary score improved in both groups, although the TAVR group reported greater improvement than to the control group. Individuals in the TAVR group reported higher SF-12 physical and mental health scores at 12 months with mean differences compared with standard care. The author concluded "among inoperable patients with severe aortic stenosis, compared with standard care, TAVR resulted in significant improvements in health-related quality of life that were maintained for at least 1 year."

The Agency for Healthcare Research and Quality's (AHRQ) original percutaneous heart valve replacement technical brief (Williams, 2010) compares the types of prosthetic heart valves currently in use and under development for percutaneous heart valve (PHV) replacement. The report concluded:

> Percutaneous valve replacement has been demonstrated to be feasible for aortic stenosis, and short-term outcomes are promising. Several companies are developing these valves, and the reported clinical experience is increasing rapidly. Percutaneous valves have the potential to expand access to valve replacement for a large group of older adults with severe valve disease and concurrent medical conditions that currently preclude surgery. Percutaneous valves also have the potential to substitute for some conventional valve replacements and expand the indications for valve replacements. However, existing data are inadequate to determine the most appropriate clinical role for these valves or the specific patient populations for whom these valves might eventually be indicated. Many unanswered questions remain pertaining to the effects—intended or unintended—of expanding the clinical indication for percutaneous heart valve replacement to groups of patients in whom this treatment modality has not yet been evaluated.

> Decision modeling, coupled with high-quality systematic reviews, could inform clinical and policy decisions in the near future. Findings from the ongoing PARTNER clinical trial should yield important efficacy data when they become available. Over the longer term, device registries could be established for the purpose of evaluating comparative effectiveness since randomized trials may not be feasible for some clinically important questions.

The Edwards SAPIEN transcatheter heart valve implant is an aortic prosthetic valve approved November 2, 2011 by the FDA through the premarket approval (PMA) process. Approval of the Edwards SAPIEN valve is based on study results evaluating the treatment of individuals with severe calcific AS who were considered to be non-operable for conventional open-heart valve replacement surgery. In these rare situations, there is currently a lack of good quality, published, peer reviewed literature to guide clinical care. While there are significant potential complications to intervention with a TAVR, in particular the risks of stroke and catheter related vascular injury, based, in part, on clinical input received and the potential to enhance the quality of life (Reynolds, 2011), the use of the transcatheter heart valve implant may be considered as beneficial as any established alternatives in this circumstance and it is reasonable to consider this option in individuals with severe aortic AS who are considered inoperable.

In 2012, the FDA expanded label indications for TAVR (TF or TA approach) for operative candidates with operative risk of greater than or equal to 8% or a risk of mortality greater than or equal to 15% with surgical valve replacement. An American College of Cardiology Foundation Expert Consensus document on Transcatheter Aortic Valve Replacement (2012) reported from the SAPIEN Aortic Biosprosthesis European Outcome (SOURCE) registry a higher risk for major bleeding events in participants who underwent the TA approach versus TF TAVR approach (3.9% vs. 2.3%). Kodali and colleagues (2012) report findings from a 2-year analysis of the randomized PARTNER trial; death for any cause for TAVR vs. surgery groups were similar (hazard ratio [HR] with TAVR, 0.90; 95% confidence interval [CI], 0.71 to 1.15; p=0.41) and at 2 years (Kaplan–Meier analysis) were 33.9% in the TAVR group (TF n=74 [30.9%]; TA n=42 [41.1%]) and 35.0% in the surgery group (p=0.78). The authors conclude:

> This 2-yr follow-up of patients in the PARTNER trial support the use of TAVR as an alternative to surgery in selected high-risk patients with aortic stenosis. The two treatments were similar with respect to mortality, reduction in cardiac symptoms, and improved valve hemodynamic. The early increase in the risk of stroke with TAVR was attenuated over time.

However, it should be noted that there is no survival benefit in the high-risk (Cohort A) population which is different from what was seen in the inoperable (Cohort B) population in the Partner trial. There is, however, an increased risk of stroke and vascular complications with associated medical and quality of life impacts. Thus, while there is efficacy data regarding use of TAVR in the high-risk group, the increased stroke and vascular complication rates are a significant negative health outcome which means that TAVR in the high-risk group is not as beneficial as the established alternative of surgical AVR.

The Edward SAPIEN XT Transcatheter Heart Valve is a second generation, balloon expandable system; the SAPIEN XT received approval June 16, 2014 by the FDA through the PMA process for relief of AS in individuals with symptomatic heart disease (Nishimura, 2017) as a result of severe native calcific AS. The FDA approval of the SAPIEN XT was based on clinical outcomes from registry data in Cohort B of the PARTNER II trial comparing the SAPIEN XT with the first generation SAPIEN THV in individuals who cannot undergo surgery (inoperable). Participants of Cohort B were randomized in a 1:1 ratio, the control arm received SAPIEN THV with RetroFlex 3 delivery system (TF approach) and participants in the treatment arm received an SAPIEN XT THV with the NovaFlex+ delivery system (TF). Primary safety and effectiveness end point was a non-hierarchical composite of death (all cause), disability major stroke and rehospitalization for AS related to valve procedure at 1 year. Serious adverse events reported at 1 year for SAPIEN XT THV (trial arm) and SAPIEN THV (control arm); death from any cause 22.34% vs. 22.50%, major stroke 4.61% vs. 5.1%, repeat hospitalization 21.63% vs. 22.51%. Device success was reported in 45.3% of the SAPIEN group and 58.5% of the SAPIEN XT group. The relative risk ratio of SAPIEN XT vs. SAPIEN was 0.759 (95% CI 0.582, 0.990), $p<0.0001$. The FDA also reviewed data from the European SOURCE XT Registry (High Risk), an international, multi-center prospective, observation registry for individuals with symptomatic AS requiring TAVR who have a high risk for operative mortality, or are inoperable. A total of 2688 participants were identified as meeting study criteria; participants received SAPIEN XT inserted using TA (33.3%), TF (62.7%), transaortic (TAo) (3.76%), or subclavian (0.3%) approach. At 30 days post THV implant with TF, TA/TAo 6.2% of participants died (3% due to cardiac death), 3.6% of population suffered a stroke and 6.6% had a major vascular complication. One year post implantation for TF, TA/TAo population, 19.5% of participants died (9.5% as a result of cardiac death), and 6.3% had suffered a stroke. Currently there is lack of randomized controlled trials demonstrating either the SAPIEN or SAPIEN XT THV superior to open surgical repair for high-risk cohort.

In August 2016, Edwards Lifesciences received FDA expanded approval for use of the SAPIEN XT and SAPIEN 3 Transcatheter Heart Valves, stating that use of TAVR is indicated for relief of AS in individuals with symptomatic heart disease due to severe calcific AS at intermediate or greater risk for open surgical therapy (that is, predicted risk of surgical mortality greater than or equal to 3% at 30 days) as determined by at least two physicians. The FDA

approval is based on reported results from the PARTNER 2 cohort, two parallel prospective, multicenter, randomized trials that enrolled 2032 individuals with severe AS, at intermediate-risk to undergo SAPIEN XT TAVR or SAVR (Leon, 2016). Participants that met enrollment criteria were stratified in cohorts according to access route (transfemoral or transthoracic) then randomized at a 1:1 ratio to undergo TAVR or SAVR. "Patients with concomitant noncomplex coronary artery disease requiring revascularization could be enrolled and treated according to the judgment of the heart team with percutaneous coronary intervention (PCI) or coronary-artery bypass graft (CABG) surgery." The primary composite end point results:

> The rate of death from any cause or disabling stroke was similar in the TAVR group and the surgery group (P=0.001 for noninferiority). At 2 years, the Kaplan-Meyer event rates were 19.3% in the TAVR group and 21.1% in the surgery group (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09; P=0.25). TAVR resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation.

Leon and colleagues concluded that:

> in intermediate-risk patients with severe symptomatic aortic stenosis, surgical and transcatheter valve replacement were similar with respect to the primary endpoint of death or disabling stroke for up to 2 years and resulted in a similar degree of lessening of cardiac symptoms.

Thourani and colleagues (2016) reported results from two prospective multicenter studies. The SAPIEN 3 observational, multicenter, post-hoc study enrolled 1077 intermediate-risk participants to TAVR with SAPIEN 3. The authors then compared 1-year outcomes in intermediate-risk populations with SAVR in the PARTNER 2A trial. To account for differences between trial baseline characteristics, authors used a prespecified propensity score analysis. At 1 year follow-up, authors included 963 participants treated with SAPIEN 3 TAVR and 747 with SAVR using the propensity score analysis.

> For the primary composite endpoint of mortality, strokes, and moderate or severe aortic regurgitation, TAVR was both non-inferior (pooled weighted proportion difference of -9.2%; 90% CI -12.4 to -6; p<0.0001) and superior (-9.2%, 95% CI -13.0 to -5.4; p<0.0001) to surgical valve replacement.

In summary, the authors concluded that the:

> TAVR and SAPIEN 3 in intermediate-risk patients with severe aortic stenosis is associated with low mortality, strokes, and regurgitation at 1 year. The propensity score analysis indicates a significant superiority for our composite outcome with TAVR compared with surgery, suggesting that TAVR might be the preferred treatment alternative in intermediate-risk patients.

The CoreValve System (including the CoreValve Evolut 23 mm, and the CoreValve 26 mm, 29 mm and 31 mm valves) is a transcatheter aortic valve approved January 17, 2014 by the FDA through the PMA process. The device is indicated for relief of AS in individuals with symptomatic heart disease due to severe native calcific AS and with native aortic annulus diameters between 18 and 29 mm who are judged by a heart team (2 cardiac surgeons and 1 interventional cardiologist), to be at extreme risk or inoperable for open surgical therapy. The FDA approval of the CoreValve device was granted without an independent device advisory panel review after reviewing the clinical outcomes in CoreValve U.S. pivotal trial - Extreme Risk Study, presented at the Transcatheter Cardiovascular Therapeutics (TCT) Committee. In June 2014, the FDA has granted expanded approval for the CoreValve System, allowing its use in individuals with severe AS who are at high mortality risk if they undergo traditional open-heart procedures, without going through an expert panel review.

Adams and colleagues (2014) reported outcomes from the CoreValve U.S. pivotal trial - High Risk Study. The multicenter study evaluated 795 eligible participants with severe AS and heart failure symptoms of NYHA class II or higher who were at increased surgical risk as determined by the heart team (two cardiac surgeons and one interventional cardiologist) who estimated the risk of death within 30 days after surgery was 15% or more and the risk of death or irreversible complications within 30 days after surgery was less than 50%. Eligible participants were randomly assigned in a 1:1 ratio to TAVR with the self-expanding transcatheter valve (n=394 intention-to-treat population; n=390 as-treated population) or to open surgical aortic-valve replacement (n=401 intention-to-treat population; n=357 as-treated population). The primary endpoint was the rate of death from any cause at 1 year. The authors reported that at 1 year, the rate of death from any cause was lower in the TAVR group than in the surgical group (14.2% vs. 19.1%; p<0.001 for noninferiority, p=0.04 for superiority). In addition, the rate of major adverse cardiovascular and cerebrovascular events at 1 year was significantly lower in the TAVR group than in the surgical group (20.4% vs. 27.3%, p=0.03). Stroke risk did not significantly differ between TAVR and open valve repair. The rates of any stroke were 4.9% in the TAVR group and 6.2% in the surgical group at 30 days (p=0.46) and 8.8% and 12.6%, respectively, at 1 year (p=0.10).

In 2020, Makkar and colleagues reported long-term clinical outcomes after TAVR versus SAVR in the intermediate-risk population (PARTNER 2; NCT01314313). The study enrolled 2032 individuals with severe, symptomatic AS at intermediate-risk and randomly assigned participants to undergo either TAVR (n=1011) or

SAVR (n=1021). The study's primary endpoint was death from any cause or disabling stroke. The authors reported no significant difference at 5 years in the incidence of death from any cause or disabling stroke between the TAVR group and the SAVR group (47.9% and 43.4%, respectively; HR, 1.09; 95% CI, 0.95 to 1.25; p=0.21). At 5 year follow-up at least mild paravalvular aortic regurgitation was more common in the TAVR group than the SAVR group (33.3% vs. 6.3%), as were repeat hospitalizations (33.3% vs 25.2%), and aortic-valve interventions (3.2% vs. 0.8%). At 5 years, the improvement in health status was similar for the TAVR and SAVR groups. The authors concluded, "Among patients with aortic stenosis who were at intermediate surgical risk, there was no difference in the incidence of death or disabling stroke at 5 years after TAVR as compared with surgical aortic-valve replacement."

In August 2019, the FDA granted approval for use of Edward SAPIEN 3, SAPIEN 3 THV systems and Medtronics CoreValve Evolut THV Systems for the treatment of individuals with severe, calcific, AS who are at low operative risk for standard SAVR. Mack and colleagues (2019) reported preliminary results from the PARTNER 3 (P3) trial (NCT02675114), a prospective, randomized, controlled, multicenter study evaluating the safety and effectiveness of the SAPIEN 3, for symptomatic individuals with severe AS at low-risk for surgery. The study compared TAVR to SAVR in individuals who are at low-risk (STS < 4%) for surgery, and 1000 participants (mean age 73) were randomized to receive TAVR (n=496) or surgery (n=454). Among all participants with severe AS who were at low surgical risk, "the rate of the composite of death, stroke, or hospitalization at 1 year was significantly lower with TAVR than with surgery." Popma and colleagues (2019) reported results from a pre-market, multicenter, international, prospective study (NCT02701283) evaluating TAVR with the Medtronic CoreValve Evolut THV systems to SAVR in individuals with severe AS (AVA of 1.0 cm^2 or less or AVA index of ≤ 0.6 cm^2 per square meter OR a mean gradient of 40 mm Hg or more or maximal aortic-valve velocity of 4.0 m or more per second) and who were at low surgical risk (≤ 3%). The as-treated cohort included 1403 assigned participants, 725 in the TAVR group and 678 in the surgery group. At 24 months, the estimated incidence of death from any cause and disabling stroke were 4.5% and 1.1% in the TAVR group versus 4.5% and 3.5% in the surgery group. The authors stated, "longer-term follow-up will be necessary to understand the implications of these various valve characteristics on structural valve deterioration and long-term outcomes." In conclusion, long-term follow-up is required to draw conclusions concerning the durability of TAVR in symptomatic individuals with severe, calcific, AS who are at low operative risk for standard SAVR to improve clinical outcomes.

In a Cochrane review, Kolkailah and colleagues (2019) evaluated TAVR versus SAVR for severe AS in adults (18 years of age or older) at low surgical risk. The review, which included 13 studies comprised of 2818 participants, found insufficient long-term evidence to support use of TAVR in symptomatic individuals with severe AS who are at low operative risk for standard SAVR. From the studies, Cochrane authors concluded that:

> Our meta-analysis indicates that, in the short term, TAVI probably has little or no mortality difference compared to SAVR to severe AS in individuals with low surgical risk. Similarly, there is probably little to no difference in risk of stroke, MI and cardiac death between the two approaches. TAVI may reduce the risk of rehospitalization but we are uncertain about the effects on LOS. TAVI reduces the risk of atrial fibrillation, AKI and bleeding. However, the benefit is offset by the increased risk of PPM implantation. Long-term follow-up data are needed to further assess and validate these outcomes, especially durability, in the low surgical risk population.

In December 2020, the ACC/AHA published updated guideline for the management of valvular heart disease in adults (Otto, 2020). The panel offered recommendations for choice of SAVR versus TAVI for individuals for whom a bioprosthetic AVR is appropriate and for whom estimated risk is not high or prohibitive. The authors new recommendations include treatment:

- For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to trans femoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision making about the balance between patient longevity and value durability (*Category 1A*)

- For symptomatic patients with severe AS who are > 80 years of age or for younger patients with a life expectancy < 10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR (*Category 1A*)

The authors include guidance for TAVI over SAVR in low-risk individuals with symptomatic severe aortic stenosis who are greater than 80 years of age. The authors summarized that:

> TAVI valves are durable to at least 5 years, and the limited data on TAVI durability is of less concern to most patients > 80 years of age because the valve durability is likely to be longer than the patient's life expectancy.

Available data beyond 5 years is not available to demonstrate valve durability over the life expectancy for younger individuals with a life expectancy less than 10 years. The ACC/AHA recommendations are based on results from the PARTNER 3 study and "Medtronic Evolut Transcatheter Aortic Valve Replacement in low risk patients" trial

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(Mack, 2019; Popma, 2019); the risk assessment methodology recommended by the guideline has not been validated with prospective testing.

Currently there is an ongoing, prospective, multicenter registry (NCT02628899) designed to assess the safety and feasibility of TAVR in individuals with symptomatic severe AS who are at low-risk (STS score ≤ 3%) for SAVR with either bicuspid or tricuspid aortic native valves. (Rogers, 2017) Estimated enrollment of 200 low-risk participants (up to 100 TAVR in bicuspid AS) with expected results in 2023.

TAVR Valve-in-Valve:

Dvir and colleagues (2014) reported results using a multinational (55 centers) valve-in valve registry that included 459 participants (mean age 77.6 years) with degenerative aortic valve bioprosthesis, undergoing valve-in-valve implantation using balloon or self-expandable THV. At 30 days post procedure, 35 (7.6%) deaths were reported; higher mortality rate was reported for stenosis group (10.5% vs. 4.3% in the regurgitation group and 7.2% in the combined group; p=0.04). There was no difference between the self-expandable and balloon expandable device groups in terms of mortality or stroke rates. There were more major/life threatening bleeding and more acute kidney injury events reported in the balloon-expandable device in terms of mortality or stroke rates, the self-expanding population had more permanent pacemaker implantation. The authors concluded, "In this registry of patients who underwent transcatheter valve-in valve implantation for degenerated bioprosthetic aortic valves, overall 1-year survival was 83.2%. Survival was lower among patients with small bioprosthetic valves and in those with predominant surgical valve stenosis."

In March 2015, the FDA expanded approval of the CoreValve System TAVR in the treatment of individuals with failure (stenosed, insufficient, or combined) of a previous open surgical bioprosthetic aortic valve (valve-in-valve implantation), identified by the heart team (two cardiac surgeons and one interventional cardiologist) to have high or greater risk for open surgical therapy (that is, Society of Thoracic Surgeons operative risk score greater than or equal to 8% or at a 15% or greater risk of operative mortality at 30 days). The FDA expanded indication is based on preliminary data collected from 143 participants in registry 6 of the "TAV-in-SAV" observational study (NCT01675440) (Dvir, 2014). In October 2015, Edwards Lifesciences received expanded approval for the SAPIEN XT THV for aortic with failure (stenosed, insufficient, or combined) of a previous open surgical bioprosthetic aortic valve (valve-in-valve implantation), identified by the heart team (two cardiac surgeons and one interventional cardiologist) to have high or greater risk for open surgical therapy (that is, Society of Thoracic Surgeons operative risk score greater than or equal to 8% or at a 15% or greater risk of operative mortality at 30

days) based on nested registry of PARTNER II trial (NCT01314313) with 197 valve-in-valve participants treated. The registry data provides initial results for use of TAVR valve-in-valve approach. Based on registry data, TAVR after failed surgical bioprosthetic valve offers a treatment option for high or greater risk individuals that are not candidates for open surgical therapy.

Paravalvular leak (PVL) is a potential risk for individuals undergoing aortic valve replacement, the incidence of PVL after TAVR is greater than in SAVR. The incorrect sizing of the TAV may lead to an incomplete seal of the prosthetic valve resulting in a PVL; advancements in technology and newer models of TAVs should reduce the number of PVLs. Although early European Registry data is promising, a randomized, comparative trial is needed to establish the efficacy and safety of repeat TAVR (TAVR-in-TAV). To date, none of the TAVR systems have received FDA approval for use in the treatment of repeat TAVR of prior TAV.

TPV:

McElhinney and colleagues (2010) reported on 124 subjects with dysfunctional right ventricular outflow tract obstruction who underwent pulmonary valve placement. The study protocol received approval by the FDA as a clinical trial under the humanitarian device exemption (HDE). This feasibility study looked at the procedural success, safety and short-term effectiveness of the Medtronic Melody transcatheter pulmonary valve in subjects with dysfunctional RVOT conduits as defined by either moderate (3+) or severe (4+) pulmonary regurgitation or mean RVOT gradient greater than or equal to 35 mm Hg. The authors concluded that:

> In this updated report from the first prospective multicenter TPV trial; we demonstrated an ongoing high rate of procedural success and encouraging short-term function of the Melody valve. The addition of two sites to the original trial protocol supports the conclusion that this technology can be adopted safely and effectively by properly trained, experienced interventional pediatric/congenital cardiologists. The fact that all reinterventions in the series were for RVOT obstruction highlights the importance of appropriate patient selection, adequate relief of obstruction at the time of Melody valve placement, and measures to prevent and manage stent fracture.

In January 2010, the Melody TPV and Ensemble Delivery System initially was cleared for market by the FDA through the Humanitarian Device Exemption (HDE) process; in January of 2015 the FDA granted premarket PMA, providing a newer, less invasive treatment option without open heart surgery for individuals with RVOT conduit regurgitation or stenosis using a less invasive procedure. According to the FDA news release in January 2010, the approval was based on clinical studies of 99 subjects in the United States and 68 subjects in Europe, demonstrating

device improved heart function and majority of subjects with noted improvement in clinical symptoms. The device showed similar, limited durability compared with existing alternative treatments; 21% of U.S. participants experienced a stent fracture, a rate consistent with stent fractures reported for the bare metal stents presently used to treat congenital heart defects of the pulmonary valve. According to the FDA new release:

> Like other valves, the Melody does not cure the heart condition and over time, the Melody may wear and require replacement. However, it is implanted without open heart surgery, can prop open the poorly functioning conduit, and keeps blood flowing in the proper direction because of the tissue valve in the Melody. These characteristics will allow an individual's conduit to function longer than usual, which can delay the need for more invasive open-heart surgery.

Currently there are no randomized controlled trials to compare the transcatheter approach to open-heart surgical technique. There are ongoing post approval studies to assess long-term clinical performance of the Melody TPV and the SAPIEN XT Transcatheter Heart Valve – Pulmonic after transcatheter implantation in participants with dysfunctional RVOT conduits.

Transcatheter Mitral Valve Repair:

An open surgical technique introduced in the early 1990s to treat mitral regurgitation (MR) involves approximating the middle scallops of the mitral leaflets to create a double orifice with improved leaflet coaptation. The MitraClip Delivery System (Abbott Vascular Inc., Santa Clara, CA) was developed as a percutaneous method to accomplish a similar repair. Using a trans-septal approach, general anesthesia, fluoroscopy, and echo guidance, the clip device is centered over the mitral orifice, passed into the left ventricle, and then pulled back to grasp the mitral leaflets creating a double orifice. The MitraClip System consists of implant catheters and the MitraClip permanent implant device.

A prospective, multi-center, single-arm feasibility, safety, and efficacy trial of the MitraClip system was reported by Feldman and colleagues (2009). A total of 107 participants with 3 to 4+ MR meeting ACC/AHA guidelines for intervention were treated with the device. Ten (9%) had a major adverse event, including 1 non-procedural death. Overall, 79 (74%) participants achieved acute success, and 51 (64%) of those achieving acute success were discharged with MR of 1+ or less. Thirty-two (30%) individuals required open mitral valve surgery within 3 years. At 12 months, 50 of 76 (66%) individuals with acute procedural success remained free from death, mitral valve surgery, or MR >2+ (primary efficacy endpoint). Within this cohort, 23 participants with functional (not degenerative) MR had similar acute results and durability.

Feldman and colleagues (2011) reported on the EVEREST II trial in which 279 operable participants, with moderately severe (3+) or severe (4+) MR were enrolled at a 2:1 ratio to undergo either percutaneous mitral valve repair (n=184) or conventional surgery to repair or replace the mitral valve (n=95). The overall rates of achieving a composite efficacy endpoint were 55% in the percutaneous repair group and 73% in the conventional surgery group at 12 months. The rates of the components of the primary end points for the percutaneous repair versus conventional surgery were reported as follows: death rate of 6% for both groups; surgery for mitral-valve dysfunction, 20% versus 2%; and MR grade (3+) to (4+), 21% versus 20% at 12 months. The primary safety endpoint was a composite of major adverse events (MAEs) within 30 days. MAE occurred in 15% of participants in the percutaneous-repair group and 48% of participants in the surgery group at 30 days. At 12 months, both groups had improved left ventricular size, New York Heart Association functional class and quality-of-life measures, as compared with baseline. Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery at 12 months, the procedure was associated with a lower adverse event rate. The authors concluded "longer-term follow-up will provide additional data to better understand percutaneous treatment of mitral regurgitation."

Mauri and colleagues (2013) reported 4-year results from the EVEREST II trial. At 48 months, the composite end point of freedom from death, surgery for mitral valve dysfunction, and 3+ or 4+ MR was 39.8% in the transcatheter mitral valve repair arm versus 53.4% in the surgical arm (p=0.070). Participants treated with transcatheter mitral valve repair more commonly underwent surgery to treat residual MR compared to the conventional mitral valve surgery group with a rate of 20.4% versus 2.2% (p<0.0001) at 1 year and 24.8% versus 5.5% (p<0.001) at 4 years. The authors concluded:

> At 4 years, surgery remains the standard of care for treatment of MR among eligible patients. Percutaneous repair is associated with similar mortality and symptomatic improvement but a higher rate of MR requiring repeat procedures, and less improvement in left ventricular dimensions than surgery. Although percutaneous repair of the mitral valve to treat MR was associated with a higher rate of residual MR at 1 year, there was no difference in later occurrence of MR or mitral valve intervention between 1-year and 4-year follow-up.

The MitraClip System obtained CE Mark approval in March 2008 in Europe. Maisano and colleagues (2013) reported results from the ACCESS-EU registry study. ACCESS-EU was a prospective, nonrandomized, post-approval study which enrolled at 14 sites a total of 567 subjects with significant MR (77.1% functional; 22.9% degenerative) treated with MitraClip therapy in Europe. A total of 85% of participants were in NYHA functional

class III or IV, and 53% had an ejection fraction ≤ 40%. Subjects in this registry were older and at higher surgical risk than those studied in the EVEREST II comparison trial. A total of 19 participants who underwent a MitraClip implantation died within 30 days after the procedure. The Kaplan-Meier freedom from mortality at 1 year was 81.8%. Among participants undergoing the MitraClip implantation, a total of 98 (17.3%) deaths were reported within 12 months. There were no device embolizations. Thirty-six participants (6.3%) required MV surgery within 12 months of the procedure. The severity of MR improved at twelve months compared to baseline (p<0.001), with 78.9% of participants with MR 2+ or less. At 12 months, 71.4% of participants were in NYHA Class I or II.

Whitlow and colleagues (2012) reported acute and 12-month results from a study of a high mitral valve operative risk cohort (EVEREST II High Risk Study (HRS). All participants had congestive heart failure (89% NYHA Class III or IV), and the majority had a history of coronary artery disease with more than half having had prior cardiac surgery. Individuals were required to have symptomatic MR (3+ to 4+) and an estimated surgical mortality rate of greater than or equal to 12% (Society of Thoracic Surgeons [STS] calculator). The study enrolled 78 participants (46 functional MR; 32 degenerative MR) for percutaneous mitral valve repair with the MitraClip device. Mean age was 77 years. Outcomes of those treated with MitraClip repair (HRS cohort) were contrasted with a comparator group of 58 participants screened concurrently. Twenty-two of the screened comparator group subjects were not included due to lack of institutional review board approval, lack of informed consent, or inability to contact the participant. Of the remaining 36 subjects, 8 met HRS eligibility criteria but were not enrolled in the HRS because enrollment had closed or they elected to not enroll. Seven of the comparator group were judged eligible based on echo assessment of MR severity, but anatomic eligibility based on transthoracic echo was not confirmed. The remaining 21 subjects in the comparator group met all eligibility criteria for HRS except for 1 or more anatomic criteria related to MitraClip placement. The comparison group either received standard medical management (86%) or open mitral valve surgery (14%). STS predicted surgical mortality in the MitraClip group was 14.2% and 14.9% in the comparator group.

The major effectiveness end points at 12 months for the HRS cohort were survival, survival and MR ≤ 2+, NYHA functional class, LV measurements, SF-36 Health Survey quality of life, and rehospitalizations for CHF. The 30 day procedure-related mortality rate was 7.7% in the HRS and 8.3% in the comparator group (p=NS). The 12-month survival rate was 76% in the HRS and 55% in the concurrent comparator group (p=0.047). At 12 months, 78% of the surviving HRS cohort had MR grade of ≤ 2+ and both LV end-diastolic and end-systolic volume improved along with NYHA functional class (74% NYHA class I/II versus 89% class III/IV at baseline; p<0.0001). SF-36 quality of life measures at 12 months were improved (32.1 vs 36.1; p=0.014) and annual rate of hospitalization for CHF in surviving HRS cohort participants decreased from baseline for those subjects with available matched data.

There are several limitations to the EVEREST II HRS study. The "comparator" group was recruited retrospectively and was small in size. A randomized comparison of treatment arms was not performed. Follow-up was limited to 12 months. A portion of the individuals in the comparator group did not meet anatomic criteria for MitraClip placement and, therefore, was not directly comparable. In addition, the functional and echocardiographic data at 12 months may overestimate the benefit of the procedure since measures prior to death of non-surviving subjects were not included. The early results at 1 year of the EVEREST II HRS study suggests the MitraClip device may reduce MR in a subset of individuals deemed at high-risk for mitral valve surgery and result in improvement in clinical symptoms and left ventricular function. However, at this time, there is insufficient published evidence in the medical literature to demonstrate a safety and durable efficacy benefit over standard therapies.

The FDA granted PMA approval October 2013 for the MitraClip device. Its labeled indication is for percutaneous reduction of symptomatic mitral regurgitation (MR greater than or equal to 3+) due to a *primary* abnormality of the mitral valve (degenerative MR) in individuals who have been determined to be at prohibitive risk for mitral valve surgery. The FDA Approval of the MitraClip Clip Delivery System was granted based on unpublished trial results from 127 individuals with symptomatic mitral regurgitation due to degenerative MR included in the EVEREST II HRR and REALISM HR registries. The outcomes of this combined cohort were compared with 65 individuals with degenerative MR in a Duke University Medical Center database (Duke High Risk Cohort) who were managed non-surgically. Kaplan-Meier curves showed mortality in the MitraClip cohort was 6.4% at 30 days and 24.8% at 12 months compared to 10.9% at 30 days and 30.6% at 12 months in the Duke High Risk DMR cohort. The analysis cohort was developed post-hoc which limits the interpretation of the data and the results were described as "only descriptive". Currently there are ongoing post-approval studies evaluating the long-term effectiveness of transcatheter mitral valve leaflet repair in this population.

~~The 2017 AHA/American College of Cardiology (ACC) focused update of the 2014 guideline for the management of valvular heart disease in adults maintains a *Class IIb recommendation* for transcatheter mitral valve repair for treatment of heart failure including:~~

> ~~Severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal GDMT for heart failure (HF).~~

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Obadia and colleagues (2018) reported results from the MITRA-FR trial (NCT01920698) for off-label use of the MitraClip; the multicenter, randomized, open-label, controlled phase 3 trial conducted in France enrolled participants with severe *secondary* MR with regurgitant volume of greater than 30 ml per beat or effective regurgitant orifice area of greater than 20 mm^2. Participants were randomized in a 1:1 ratio to undergo percutaneous mitral valve repair in addition to receiving medical therapy (intervention group; n=152) or to receive medical therapy alone (control group; n=152). Additional inclusion criteria for the study included participants with EF between 15-40% and chronic heart failure symptoms (NYHA functional class II, III or IV). Individuals who had prior mitral valve surgery were excluded from the study. The primary efficacy outcome was a composite of death of any cause and unplanned hospitalization for HF; at 12 months the rate of primary outcome in the intervention group was 54.6% (n=83) and 51.3% (n=78) in the control group (odds ratio, 1.16; 95% confidence interval [CI], 0.73 to 1.84; p=0.53). The rate of death from any cause in the intervention group was 24.3% (n=37) and 22.4% (n=34) in the control group (hazard ratio, 1.11; 95% CI, 0.69 to 1.77). A total of 74 participants in the intervention group (48.7%) and 72 participants in the control group (47.4%) had unplanned hospitalization for heart failure (hazard ratio, 1.13; 95% CI, 0.81 to 1.56). The authors concluded that "the rate of the composite primary outcome of death or unplanned hospitalization for heart failure at 12 months did not differ significantly between the intervention group and the control group."

In December 2020, ACC/AHA guideline for the management of valvular heart disease (Otto, 2020), the authors provide recommendations for transcatheter edge-to-edge repair intervention for chronic primary MR and secondary MR :

Chronic Primary MR

- In severely symptomatic patients (NYHA class III or IV) with primary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) is reasonable if mitral value anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year (*Category 2a*)

Secondary MR

- In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF <50%) who have persistent symptoms (NYHA class II, III, or IV) while on optimal GDMT for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on TEE and with LVEF between 20% and 50%, LVESD ≤70 mm, and pulmonary artery systolic pressure ≤70 mm Hg (*Category 2a*)

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The committee recommendations for TMVR with the MitraClip are based on results from the EVEREST II, MITRA-FR trial and COAPT trials previously outlined in this document.

On March 14, 2019 the FDA approved the MitraClip™ NTR/XTR Clip Delivery System for the treatment of *secondary/functional mitral regurgitation* in select individuals with heart failure who remain symptomatic despite guideline-directed medical therapy (GDMT). The FDA approval is based on recent evidence reported in the COAPT trial. The Stone and colleagues (2018) reported findings from the COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation) (NCT01626079) trial, a multicenter randomized, controlled, open-label trial with the MitraClip device in symptomatic participants with HF and moderate-to severe or severe *secondary* MR who remained symptomatic with maximal guideline directed medical therapy. Participants were randomly assigned to receive transcatheter mitral valve repair with MitraClip plus medical therapy (device group; n=302) or medical therapy alone (control group; n=312). The primary efficacy outcome was all hospitalizations from HF up to a 24-month follow-up period; the annualized rate of hospitalizations was 35.8% per "patient-year" in the device group compared to 67.9% in the control group (HR, 0.53; 95% CI, 0.40 to 0.71; p<0.001). "The rate of freedom from device-related complications at 12 months was 96.6% (lower 95% confidence limit, 94.8%), a rate that exceeded the objective performance goal of 88.0% for the primary safety endpoint (p<0.001)." In the device group the rate of death that occurred from any cause within 24 months was 29.1% as compared with 46.1% in the control group (hazard ratio, 0.62; 95% CI, 0.46 to 0.82; p<0.001); after adjustments for differences in medical management for HF between trial groups, there was lower mortality (HR, 0.65, 95% CI, 0.49 to 0.86; P=0.003). In participants with HF and moderate-to-severe or severe MR that were symptomatic after maximum medical therapy the authors concluded that "transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone. The rate of freedom from device-related complications exceeded a prespecified safety threshold." There were conflicting results reported between the MITRA-FR trial and the COAPT trial which warrants further long-term study in use of the MitraClip in treatment of HF for individuals with moderate-to-severe or severe MR. Currently there is an *ongoing* study evaluating the MitraClip in mitral valve insufficiency to standard of care, the Reshape-HF2 (RandomizEd Study of tHe MitrACliP Device in Heart Failure Patients with Clinically Significant Functional Mitral Regurgitation) (NCT02444338) trial. Estimated enrollment of 420 participants, evaluating the safety and effectiveness of the MitraClip System in the treatment of significant functional mitral regurgitation insufficiency in individuals with NYHA functional class II to class IV chronic HF with expected results in March 2021.

The CARILLON Mitral Contour System, an implantable device with a percutaneous catheter delivery system, is intended to reduce mitral annulus dilatation upon deployment, thereby significantly reducing functional mitral

regurgitation (FMR). Rapidly delivered via the venous vasculature, CARILLON has the potential to treat most heart failure individuals in a minimally invasive fashion. There is an ongoing clinical trial evaluating the use of the CARILLON system to treat individuals with heart failure as a result of FMR. Presently, the CARILLON system has not been granted final approval by the FDA for this indication.

In December 2018, Edwards Lifesciences, the manufacturer of the SAPIEN 3 THV System and SAPIEN 3 Ultra THV System received FDA approval, for the use in individuals with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic *mitral* valve who are judged by a heart team, including a cardiac surgeon, to be at high risk or greater for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator). The FDA approval for valve-in-valve for transcatheter mitral valve repair cohort was based on extracted data from the multicenter STS/ACC Transcatheter Valve Therapy Registry (TVTR) Analysis. The study enrolled 311 participants (SAPIEN XT group, n=241; SAPIEN 3, n=70); mortality rate at discharge was 5.1% (n=16) and at 30- day follow-up there were 20 deaths (6.8%) reported. For the 30-day follow-up 84.1% (n=244) of participants completed follow-up visit and 15.9% (n=46) missed visit. The long-term effect of valve-in-valve transcatheter mitral valve repair procedures is not known and requires further study. (Product Label Information, 2019)

Transcatheter Tricuspid Valve Repair or Replacement:

Tricuspid valve repair or replacement via a transcatheter approach, devices for transcatheter tricuspid valve repair (TTVR) and replacement are in early stages of development for the treatment of tricuspid regurgitation. There are early studies evaluating use of two TTVR devices, the TriClip Delivery System, essentially the same clip delivery used for the mitral valve and the Cardioband Valve System delivery via transfemoral approach (TRI-REPAIR Study). Individual selection criteria for percutaneous tricuspid valve replacement are based on limited data. Currently there are no FDA-approved devices to be delivered in the tricuspid position.

Background/Overview

Transcatheter heart valve replacement is a less invasive alternative to conventional open-heart surgery. This alternative approach to conventional valve replacement surgery does not require heart-lung bypass. A catheter inserted using a TF, TA, or transaortic approach allows the introduction of an expandable prosthetic heart valve

which is then delivered to the diseased native valve. Two minimally invasive alternatives to surgical mitral valve repair include transcatheter leaflet repair and percutaneous annuloplasty. The purpose of transcatheter mitral valve leaflet repair is to keep the two valve leaflets more closely fitted together, thereby reducing regurgitation. Percutaneous annuloplasty attempts to reshape the mitral annulus using catheters guided through the vasculature to reach the heart to reduce regurgitation.

The FDA has approved the following THV devices used for marketing which include the following:

SAPIEN THV Systems (that is, SAPIEN XT™, SAPIEN 3 Transcatheter Heart Valve, and SAPIEN 3 Ultra Transcatheter Heart Valve] [Edwards Lifesciences, Inc., Irvine, CA Edward Lifesciences])

- *The SAPIEN XT Transcatheter Heart Valve*, model 9300TFX, 23, 26, and 29 mm, and accessories (NovaFlex+ delivery system, models 9355FS23, 9355FS26, and 9355FS29, with crimp stopper and Qualcrimp crimping accessory) received FDA approval in June 2014 for relief of AS in individuals with symptomatic heart disease due to severe native calcific AS, in October 2015 the FDA expanded use for individuals with failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve, with native anatomy appropriate for the 23, 26, or 29 mm valve system, who are judged by a heart team including a cardiac surgeon, to be at high or greater risk for open surgical therapy (that is, Society of Thoracic Surgeons operative risk score ≥ 8% or at a ≥ 15% risk of mortality at 30 days).

- *The SAPIEN 3 Transcatheter Heart Valve*, Model 9600TFX, 20, 23, 26 and 29 mm, and accessories were granted FDA approval in June 2015. This is the third generation SAPIEN THV to receive approval for use in individuals with aortic valve stenosis who are inoperable or at high risk for death or complications associated with open-heart surgery. The major design change adds a skirt at the base of the valve to minimize leakage around the valve. According to the FDA, "clinical data showed that the SAPIEN 3 Transcatheter Heart Valve is superior to the first generation SAPIEN Transcatheter Heart Valve, with significantly less leakage through and around the valve." On June 5, 2017 the FDA approved expanded use of the SAPIEN 3 Transcatheter Heart Valve, Model 9600TFX for treatment of individuals with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

- Edwards Lifesciences received expanded approval by the FDA for the *SAPIEN XT* and *SAPIEN 3 Transcatheter Heart Valve* in August, 2016, for use in the treatment of individuals with symptomatic heart disease due to severe native calcific AS who are judged by a Heart Team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons [STS] risk score and other clinical co-morbidities unmeasured by the STS risk calculator) (SAPIEN XT, SAPIEN 3 Product Information, 2016).

- *The SAPIEN 3 Ultra Transcatheter Heart Valve* with the Edwards Certitude delivery system and accessories received FDA approval on December 28, 2018 for TAVR in severe, symptomatic AS in individuals who are determined to be at intermediate or greater risk of open-heart surgery. The device is also indicated for individuals with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic (aortic or mitral) valve who are judged by a heart team, including a cardiac surgeon, to be at high risk or greater for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

- On August 16, 2019 the FDA granted expanded approval for the *Edward SAPIEN 3 THV and SAPIEN Ultra THV Systems* for the relief of AS in individuals with symptomatic heart disease due to severe native calcific AS who are judged by a heart team, including a cardiac surgeon, to be appropriate for the THVR therapy. The systems are also approved for use in the treatment of symptomatic individuals with heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (that is, predicted risk of surgical mortality greater than or equal to 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator). *Long-term follow-up is required to draw conclusions concerning the durability of TAVR in symptomatic individuals with severe, calcific, AS who are at low operative risk for standard SAVR to improve clinical outcomes.*

CoreValve Systems *(that is*, CoreValve™ Evolut ™ R, CoreValve™ Evolut™ PRO and CoreValve™ Evolut™ PRO+ Systems [Medtronic, Inc., Santa Ana, CA])

- *CoreValve Evolut R and CoreValve Evolut PRO systems* were granted FDA approval on March 20, 2017 for use in individuals with *symptomatic* heart disease due to either severe native calcific AS or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart

team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (that is, Society of Thoracic Surgeons predicted risk of operative mortality score ≥ 8% or at a ≥ 15% risk of mortality at 30 days). The device is a repositionable, self-expanding valve aimed to decrease paravalvular leaks. July 10, 2017 the FDA expanded FDA approval of the CoreValve System, CoreValve Evolut System and CoreValve Evolut PRO System TAVR for treatment of individuals with severe AS who are at intermediate or greater risk for open-heart surgery and have a risk of mortality of ≥ 3 percent at 30 days following procedure. The risk assessment is determined by a heart team, including a cardiac surgeon and interventional cardiologist). The FDA approval is based on 2 year results from the landmark SURTAVI trial (NCT01586910), a randomized study comparing TAVR (CoreValve System) with surgical aortic valve replacement in individuals with severe, symptomatic AS at intermediate surgical risk. In individuals with severe AS at intermediate surgical risk, TAVR was found to be a noninferior alternative to SAVR (Reardon, 2017).

- On August 16, 2019 the FDA granted expanded approval for the *CoreValve Evolut R, CoreValve PRO and CoreValve PRO+ Systems* for use in the relief of AS in symptomatic individuals with heart disease due to severe native calcific AS who are judged by a heart team, including a cardiac surgeon, to be appropriate for the THVR therapy. The devices are also indicated for use in individuals with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (that is, STS predicted risk of operative mortality score greater than or equal to 8% **or** at a greater than or equal to 15% risk of mortality at 30 days). Popma and colleagues (2019) concluded, "*Longer-term follow-up will be necessary to understand the implications of these various valve characteristics on structural valve deterioration and long-term outcomes."*

LOTUS Edge Valve System (Boston Scientific, Marlborough, MA)

- The *LOTUS Edge Aortic Valve System* for transcatheter deliver in individuals with severe AS at high-risk for surgical aortic valve replacement. The LOTUS Edge is the only FDA approved TAVR device that allows the physician to reposition and completely recapture the valve once it has been fully deployed. The device has an adapted seal that minimizes paravalvular regurgitation or leak by conforming to the native abortive valve. The LOTUS Edge Valve System is indicated for relief of AS in patients with symptomatic heart disease due to severe native calcific AS (AVA of ≤ 1.0 cm2 or index of ≤ 0.6 cm2/m2) who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicated risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical

comorbidities unmeasured by the STS risk calculator). The FDA approval is based on data REPRISE 3 data in high-risk individuals, the first head-to head comparison of two TAVR valves. On November 17, 2020 Boston Scientific announced a voluntary recall of all unused inventory of the LOTUS edge Aortic Valve System due to complexities associated with product delivery.

The FDA has approved the following TPV for marketing:

Medtronic Melody® transcatheter pulmonary valve [Medtronic, Inc., Minneapolis, MN])

- The Melody Transcatheter Pulmonary Valve (TPV) has an HDE approval from the FDA and is authorized by Federal law (USA) for use in pediatric and adult candidates with a regurgitant or stenotic RVOT conduit (greater than or equal to 16 mm in diameter when originally implanted). The effectiveness of this device for this use has not been demonstrated. FDA approval has been granted for devices for specific indications, through the HDE process. The HDE approval process is applicable to devices intended to benefit individuals in the treatment or diagnosis of conditions or diseases that affect fewer than 4000 individuals in the U.S. per year. An HDE application does not require submission of the results of scientifically valid clinical investigations demonstrating the effectiveness of the device for its intended use. However, the application must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury and that the probable health benefit outweighs the risks from its use.

SAPIEN XT THV (Edwards Lifesciences, Inc., Irvine, CA Edward Lifesciences])

- In 2016, the SAPIEN XT THV and delivery system received expanded approval by the FDA for use in children and adults with a dysfunctional, non-compliant RVOT conduit with a clinical indication for intervention and moderate or greater pulmonary regurgitation and/or mean RVOT gradient greater than or equal to 35 mmHg. The procedure is contraindicated in individuals with an inability to tolerate anticoagulation/antiplatelet regimen and present with active bacterial endocarditis.

Definitions

Aortic valve stenosis: Also known as aortic stenosis, this form of valvular heart disease is characterized by narrowing of the aortic valve opening.

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Congenital heart disease (CHD): Heart problems present at birth.

Humanitarian Device Exemption (HDE): Similar to a PMA application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose and does not pose an unreasonable or significant risk of illness or injury. The use of the device is limited to 4000 or less individuals per year.

Mitral regurgitation (also known as mitral insufficiency): A disorder in which the heart valve that separates the upper and lower chambers on the left side of the heart does not close properly, resulting in leakage of blood backward through the mitral valve each time the left ventricle contracts and increased pressure and congestion in the lungs.

Pre-Market Approval (PMA): The most stringent type of device marketing application required by the FDA. A PMA is an application submitted to the FDA to request clearance to market or to continue marketing of a Class III medical device. Class III medical devices are those devices that present significant risk to the individual and/or require significant scientific review of the safety and effectiveness of the medical device prior to commercial introduction. Frequently the FDA requires follow-up studies for these devices.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
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

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33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels)
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery)
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

ICD-10 Procedure

02RF3JH	Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach
02RF3JZ	Replacement of aortic valve with synthetic substitute, percutaneous approach
02RF4JZ	Replacement of aortic valve with synthetic substitute, percutaneous endoscopic approach
02RH3JH	Replacement of pulmonary valve with synthetic substitute, transapical, percutaneous approach
02RH3JZ	Replacement of pulmonary valve with synthetic substitute, percutaneous approach
02RH4JZ	Replacement of pulmonary valve with synthetic substitute, percutaneous endoscopic approach

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:

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For the codes listed above when criteria are not met.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
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
33999	Unlisted procedure, cardiac surgery [when specified as transcatheter replacement of tricuspid heart valve]
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 (eg, thoracotomy, transapical)
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
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed [Note: code effective 07/01/2021]

ICD-10 Procedure	
02RG3JH	Replacement of mitral valve with synthetic substitute, transapical, percutaneous approach
02RG3JZ	Replacement of mitral valve with synthetic substitute, percutaneous approach
02RG4JZ	Replacement of mitral valve with synthetic substitute, percutaneous endoscopic approach

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02RJ4JZ	Replacement of tricuspid valve with synthetic substitute, percutaneous endoscopic approach

ICD-10 Diagnosis

All diagnoses

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Government Agency, Medical Society, and Other Authoritative Publications:

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Websites for Additional Information

1. American Heart Association. Available at: https://www.heart.org/. Accessed on January~~April~~ 0~~4~~3, 2021~~0~~.
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http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/default.htm. Accessed on JanuaryApril 043, 20210.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Revised	02/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised MN medically necessary statement for TAVR to include criteria for low open surgical risk in individuals 80 years of age or older. Updated Rationale, Background, References, and Websites sections. Updated Coding section with 07/01/2021 CPT changes; added 0646T.
	01/25/2021	Updated first TAVR MN statement using a U.S Food and Drug Administration (FDA) approved device, the change is to correct a typographical error in the criteria hierarchy formatting and involves correcting criteria 'B' to appear as criteria 'A.4.'
Revised	05/14/2020	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. Added INV/NMN statement for valve-in-valve transcatheter mitral valve repair for all indications. Updated Rationale, Background, References, and Websites sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale, Background, References and Websites sections. Updated Coding section with 01/01/2020 CPT changes; added 0569T, 0570T.
Revised	06/06/2019	MPTAC review. Added INV/NMN statement for use of transcatheter tricuspid valve repair or replacement for all indications. Updated Description, Rationale, References and Websites sections. Updated Coding section with 07/01/2019 CPT changes; added 0544T, 0545T.
Revised	03/21/2019	MPTAC review. Reformatted MN section, removing device names from position statements and list of comorbid conditions and contraindications. Added "Note" to refer to background section of document for list of FDA approved THV devices used for TAVR and TPVs. Revised Transcatheter (aortic, pulmonic, valve-in-valve) INV/NMN statements to NMN. Removed INV/NMN statement for TAVR with any device other than those listed above. Removed INV/NMN statement for transcatheter valve implantation in other valve locations. Updated Description, Rationale, Background, References, Websites and Index sections.
Revised	11/08/2018	MPTAC review. Revised MN statements for TAVR, removing "end stage renal disease requiring chronic dialysis or creatinine clearance" from list of comorbid conditions or contraindications that would preclude the expected benefit from aortic stenosis correction. Updated Rationale, Background, References and Websites sections.

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Revised	03/22/2018	MPTAC review. Updated MN statement for TAVR devices removing "individual was offered surgery but refused" as contraindication to TAVR. Updated Rationale, References and Websites sections.
	01/01/2018	The document header wording updated from "Current Effective Date" to "Publish Date." Updated Coding section with 01/01/2018 CPT changes; added codes 0483T and 0484T.
Revised	08/03/2017	MPTAC review. Revised MN statement for TAVR with the CoreValve System, CoreValve Evolut R System and CoreValve Evolut PRO System to include coverage for individuals at intermediate or greater risk when criteria met. Updated Background, References and Websites sections.
Revised	05/04/2017	MPTAC review. Revised MN statement for TAVR with CoreValve System to include the CoreValve Evolut R System and CoreValve Evolut PRO System. Updated Description, Rationale, Background, Index, References and Websites sections.
Reviewed	02/02/2017	MPTAC review. Updated Rationale, Background, References and Websites sections.
Revised	11/03/2016	MPTAC review. Updated formatting in Position Statement section. Revised MN statement for TAVR with the Edwards SAPIEN, SAPIEN XT or SAPIEN 3 Transcatheter Heart Valve to include coverage for individuals at intermediate or greater risk when criteria met. Updated Rationale, Background, References, Websites, and Index sections.
Revised	08/04/2016	MPTAC review. Added MN statement for TAVR with an FDA-approved transcatheter heart valve system (SAPIEN XT or CoreValve System) for the treatment of individuals with a previous open surgical bioprosthetic aortic valve (valve-in-valve) when criteria met. Clarified contraindications for TAVR performed with the Edwards SAPIEN, SAPIEN XT, SAPIEN 3 or CoreValve system. Reformatted MN criteria. Updated Rationale, References and Websites sections.
	01/01/2016	Updated Coding section with 01/01/2016 CPT changes; removed 0262T deleted 12/31/2015.
Revised	11/05/2015	MPTAC review. Defined abbreviation in TAVR medically necessary criteria. Added SAPIEN 3 to TAVR medically necessary statement. Updated Description, Rationale, Background, References and Websites. Removed ICD-9 codes from Coding section.

Revised	11/13/2014	MPTAC review. Added the Edwards SAPIEN XT THV as medically necessary when criteria met. Clarified TAVR medically necessary criteria for CoreValve System. Updated Description, Rationale, Background and Index sections. Updated Coding section with 01/01/2015 CPT changes; removed 0343T, 0344T deleted 12/31/2014.
Reviewed	08/14/2014	MPTAC review. Updated Description, Rationale, Background, References, Websites.
Revised	05/15/2014	MPTAC review. Changed title to: *Transcatheter Heart Valve Procedures.* Added medically necessary statement for transcatheter aortic valve replacement with the CoreValve system. Revised investigational and not medically necessary statement transcatheter aortic valve replacement with any device other than those listed above as medically necessary. Added investigational and not medically necessary statements addressing transcatheter mitral valve repair using leaflet repair (e.g. MitraClip Clip Delivery System) and transcatheter mitral valve repair using percutaneous annuloplasty (e.g. Carillon Mitral Contour System). Updated Description, Rationale, Background, Index, Definitions, References and Websites.
Revised	02/13/2014	Medical Policy & Technology Assessment Committee (MPTAC) review. Medically necessary criteria updated, removed requirement that the delivery of the TAVR be through a transfemoral approach. Added TAVR with any device other than the Edwards SAPIEN transcatheter heart valve as investigational and not medically necessary. Removed alternate approaches from investigational and not medically necessary statement. Updated Rationale, Background, Coding, Index, References and Websites.
	01/01/2014	Updated Coding section with 01/01/2014 CPT changes; removed 0318T deleted 12/31/2013.
Revised	02/14/2013	MPTAC review. Added medically necessary criteria for transcatheter pulmonary valve and revised investigational and not medically necessary statement for transcatheter pulmonary valve. Updated Rationale, Coding, References and Websites.
	01/01/2013	Updated Coding section with 01/01/2013 CPT changes; removed 0256T, 0257T, 0258T, 0259T deleted 12/31/2012.
Revised	02/16/2012	MPTAC review. Added medically necessary criteria and investigational and not medically necessary statement for transcatheter aortic heart valve. Added

		additional investigational and not medically necessary statement to address other valves and other methods of implantation. Revised investigational and not medically necessary statement addressing transcatheter pulmonary valve Updated Rationale, Background, Coding, Index, Websites and References.
Reviewed	11/17/2011	MPTAC review. Updated Rationale, Background, Websites and References.
	10/01/2011	Updated Coding section with 10/01/2011 ICD-9 changes.
	07/01/2011	Updated Coding section with 07/01/2011 CPT changes.
New	11/18/2010	MPTAC review. Initial document development.