

TRANSCATHETER HEART VALVE PROCEDURES

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, 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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BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.

Depending on the member's specific benefit document, coverage may be available either through participation in an eligible clinical trial or through benefit coverage for promising but unproven treatments for life threatening conditions when certain conditions are met.

COVERAGE RATIONALE

Aortic Valve

Transcatheter aortic heart valve replacement is proven and medically necessary for patients with severe, symptomatic aortic stenosis who meet the following criteria:

- Patient requires valve replacement surgery but is at high risk for serious surgical complications or death from open valve replacement surgery. According to the U.S. Food and Drug Administration (FDA) approval, high risk is defined as a Society of Thoracic Surgeons (STS) predicted operative risk score of >8% or an estimated >15% mortality risk for surgical aortic valve replacement.
- Procedure is performed using a FDA approved device system
- Procedure is performed according to FDA approved labeled indications and contraindications

Pulmonary Valve

Transcatheter pulmonary heart valve replacement is unproven and not medically necessary in patients with right ventricular outflow tract dysfunction.

There is insufficient evidence in the clinical literature demonstrating the long-term efficacy and durability of catheter-delivered prosthetic pulmonary heart valves for treating right ventricular outflow tract dysfunction. See [Benefit Considerations](#) for coverage of unproven services when certain conditions are met.

Mitral Valve

Percutaneous transcatheter mitral valve leaflet repair is unproven and not medically necessary.

There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of catheter-delivered mitral valve leaflet repair devices for treating mitral regurgitation. Further results from prospective, randomized controlled trials are needed to determine device durability and the ideal candidates for the procedure. See [Benefit Considerations](#) for coverage of unproven services when certain conditions are met.

Percutaneous transcatheter mitral valve annuloplasty via the coronary sinus is unproven, not medically necessary and investigational due to lack of U.S. Food and Drug Administration (FDA) approval.

There is insufficient evidence in the clinical literature demonstrating the long-term efficacy of coronary sinus annuloplasty devices for treating mitral regurgitation. Further results from prospective, randomized controlled trials are needed to determine safety, efficacy, durability and the ideal candidates for the procedure.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT[®] Code	Description
0262T	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach
0343T	Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; initial prosthesis
0344T	Transcatheter mitral valve repair percutaneous approach including transseptal puncture when performed; additional prosthesis (es) during same session
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
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)
93799	Unlisted cardiovascular service or procedure

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DESCRIPTION OF SERVICES

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

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

Aortic Valve

The aortic valve directs blood flow from the left ventricle into the aorta. Aortic valve stenosis, a common valvular disorder in older adults, is a narrowing or obstruction of the aortic valve that prevents the valve leaflets from opening normally. When the aortic valve does not open properly, the left ventricle has to work harder to pump enough blood through the narrowed opening to the rest of the body. Reduced blood flow can cause chest pain, shortness of breath, excess fluid retention and other symptoms. Left untreated, severe aortic stenosis can lead to left ventricular hypertrophy and heart failure (ECRI, 2012a). The various stages of valvular aortic stenosis are addressed by Nishimura et al. (2014).

The gold standard for treating severe, symptomatic aortic stenosis is surgical replacement with a prosthetic valve. However, some patients are not candidates for open-heart surgery because they are too old, too frail or they suffer from another condition that would make the surgery too risky. 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 patient 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 (ECRI, 2014b; Williams et al., 2010).

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 right ventricular outflow tract (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 patients undergoing this procedure are typically children or adolescents, the bioprosthetic valve will require revisions as the patient 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 a patient's lifetime. Transcatheter pulmonary valves feature a metal, stent-like scaffold that contains a bioprosthetic valve. Access to the pulmonary valve is achieved via the femoral vein. The replacement valve is usually positioned within a preexisting pulmonary conduit (graft) (ECRI, 2012b; NICE, 2013; Medtronic Melody website).

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 (Hayes, 2014). 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 (NICE, 2009).

Transcatheter leaflet repair and percutaneous annuloplasty are two 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.

CLINICAL EVIDENCE

Aortic Valve

The body of evidence for transcatheter aortic valve replacement (TAVR) for aortic stenosis is moderately large in size and low to moderate in quality. There was one randomized controlled trial (RCT), but the bulk of the literature consisted of case series. Evidence from comparison studies suggests that TAVR and surgical aortic valve replacement (SAVR) are equally effective and superior to medical management at reducing mortality and improving symptoms in patients with severe aortic stenosis. Evidence from uncontrolled studies suggests that TAVR has a high success rate and improves function and quality of life. The procedural success rate ranged from 73% to 98%, and most studies had a success rate of approximately 97%. Studies comparing TAVR devices found no significant differences in mortality between the different treatment groups; however, the data is insufficient to draw conclusions regarding the superiority of one device over another. There is insufficient evidence to establish definitive patient selection criteria for TAVR. However, sufficient evidence exists to support the use of TAVR in patients with severe aortic stenosis who are not candidates for conventional surgical valve replacement because of significant comorbid conditions, porcelain aorta or frailty (Hayes, 2013a).

An Agency for Healthcare Research and Quality (AHRQ) technical brief states that 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 (Williams et al., 2010).

PARTNER (Placement of Aortic transcatheter valves) trial

The PARTNER trial is a two-part, multicenter, randomized controlled trial funded by Edwards Lifesciences. Cohort A compared transcatheter aortic valve replacement to surgical valve replacement. Cohort B compared transcatheter aortic valve replacement to medical therapy in patients with severe aortic stenosis who were unable to undergo surgery. (Clinicaltrials.gov number NCT00530894)

Cohort A

In a multicenter, randomized controlled trial, Smith et al. (2011) randomly assigned 699 high-risk patients with severe aortic stenosis to undergo either TAVR with a balloon-expandable bovine pericardial valve (n=348; transfemoral n=244; transapical n=104) or surgical replacement (n=351). The primary end point was death from any cause at 1 year. The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days and 24.2% and 26.8%, respectively, at 1 year. The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days and 5.1% and 2.4%, respectively, at 1 year. At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs. 3.2%). Adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%) and new-onset atrial fibrillation (8.6% vs.

16.0%). The authors concluded that in high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks.

A 2-year follow-up of patients in Cohort A reported similar outcomes in the two groups with respect to mortality, reduction in cardiac symptoms and improved valve hemodynamics. Paravalvular regurgitation was more frequent after TAVR and was associated with increased late mortality. An early increase in the risk of stroke with TAVR was attenuated over time. The authors concluded that these results support TAVR as an alternative to surgery in high-risk patients (Kodali et al., 2012). ClinicalTrials.gov number NCT00530894.

Cohort B

In the same multicenter, randomized controlled trial, Leon et al. (2010) evaluated TAVR in patients with severe aortic stenosis who were not candidates for surgery. A total of 358 patients were randomized to standard therapy (including balloon aortic valvuloplasty) (n=179) or transfemoral transcatheter implantation of a balloon-expandable bovine pericardial valve (n=179). At 1 year, the rate of death from any cause was 30.7% with TAVR, as compared with 50.7% with standard therapy. The rate of the composite end point of death from any cause or repeat hospitalization was 42.5% with TAVR as compared with 71.6% with standard therapy. Among survivors at 1 year, the rate of cardiac symptoms (New York Heart Association class III or IV) was lower among patients who had undergone TAVR than among those who had received standard therapy (25.2% vs. 58.0%). At 30 days, TAVR, as compared with standard therapy, was associated with a higher incidence of major strokes (5.0% vs. 1.1%) and major vascular complications (16.2% vs. 1.1%). In the year after TAVR, there was no deterioration in the functioning of the bioprosthetic valve. The authors concluded that in patients with severe aortic stenosis who were not suitable candidates for surgery, TAVR, as compared with standard therapy, significantly reduced the rates of death from any cause, the composite end point of death from any cause or repeat hospitalization and cardiac symptoms, despite the higher incidence of major strokes and major vascular events (Leon et al., 2010).

At 2 years, the mortality rates in Cohort B were 43.3% in the TAVR group and 68.0% in the standard therapy group. The corresponding rates of cardiac death were 31.0% and 62.4%. The survival advantage associated with TAVR at 1 year remained significant among patients who survived beyond the first year. The rate of stroke was higher after TAVR than with standard therapy (13.8% vs. 5.5%). There was an increased frequency of early ischemic strokes (≤ 30 days) but little change in the rate of late ischemic strokes (>30 days). At 2 years, the rate of rehospitalization was 35.0% in the TAVR group and 72.5% in the standard-therapy group. TAVR, as compared with standard therapy, was also associated with improved functional status. The data suggest that the mortality benefit after TAVR may be limited to patients who do not have extensive coexisting conditions. The authors concluded that among appropriately selected patients with severe aortic stenosis who were not suitable candidates for surgery, TAVR reduced the rates of death and hospitalization, with a decrease in symptoms and an improvement in valve hemodynamics that were sustained at 2 years of follow-up (Makkar et al., 2012). ClinicalTrials.gov number NCT00530894.

In a multicenter, randomized, noninferiority trial, Adams et al. (2014) reported that TAVR, using a self-expanding bioprosthesis (CoreValve), had a significantly higher rate of survival at one year than SAVR in patients with severe aortic stenosis and an increased surgical risk. A total of 795 patients were randomly assigned in a 1:1 ratio to TAVR with the CoreValve (TAVR group) or to SAVR (surgical group). The rate of death from any cause at one year was significantly lower in the TAVR group than in the surgical group (14.2% vs. 19.1%) with an absolute reduction in risk of 4.9 percent. Results were similar in the intention-to-treat analysis where the event rate was 13.9 percent in the TAVR group compared to 18.7 percent in the surgical group. The survival benefit with TAVR was consistent across clinical subgroups. ClinicalTrials.gov #NCT01240902.

In a prospective, multicenter, nonrandomized study, Popma et al. (2014) evaluated the safety and efficacy of the CoreValve transcatheter heart valve for the treatment of severe aortic stenosis in patients at extreme risk for surgery. Forty-one sites recruited 506 patients, of whom 489 underwent treatment with the CoreValve device. The rate of all-cause mortality or major stroke at 12 months was 26.0% vs. 43.0%. Individual 30-day and 12-month events included all-cause mortality (8.4% and 24.3%, respectively) and major stroke (2.3% and 4.3%, respectively). Procedural events at 30 days included, life threatening/disabling bleeding (12.7%), major vascular complications (8.2%) and need for permanent pacemaker placement (21.6%). The frequency of moderate or severe paravalvular aortic regurgitation was lower 12-months after self-expanding TAVR (4.2%) than at discharge (9.7%).

Two nonrandomized studies compared specific TAVR devices (Attias et al., 2010; Wenaweser et al., 2011). Although there were no significant differences in mortality between the different treatment groups, further studies are needed to draw conclusions regarding the superiority of one device over another.

Several national TAVR registries were identified in the literature. Published results indicate that use of the SAPIEN and CoreValve devices was fairly equal, and the transfemoral approach was used approximately 3 times as often as the transapical approach. Conversion to surgical valve replacement occurred in 0.4% to 4% of procedures. Procedural success was very high and ranged from 91% to 99%. Procedural mortality was low and ranged from 0.4% to 3%. Survival at 30 days ranged from 87% to 95% and at 1 year from 63% to 100%, depending on the device and approach used (Gilard et al., 2012; Ussia et al., 2012; Bosmans et al., 2011; Thomas et al., 2011; Eltchaninoff et al., 2011; Zahn et al., 2011; Moat et al., 2011; Rodés-Cabau et al., 2010).

A meta-analysis of the adverse effects associated with TAVR included over 16,000 patients in 49 studies. Khatri et al. (2013) found that the need for a permanent pacemaker was the most common adverse outcome (13.1%) and was 5 times more common with the CoreValve than the Edwards SAPIEN valve. Vascular complications were also common (10.4%) and was highest with the transarterial implantation of the Edwards SAPIEN valve (22.3%). Acute renal failure was the third most common complication, occurring in 4.9% of patients. Overall 30-day and 1-year survival after TAVR were 91.9% and 79.2%, respectively.

A National Institute for Health and Care Excellence (NICE) guidance document states that the evidence on the safety of TAVR for aortic stenosis shows the potential for serious but well-recognized complications. For patients with aortic stenosis who are considered to be unsuitable for SAVR, the evidence on the efficacy of TAVR is adequate. For patients with aortic stenosis for whom SAVR is considered suitable but poses a high risk, the evidence on the efficacy of TAVR is inadequate. NICE encourages clinicians to enter suitable patients into a clinical trial. For patients with aortic stenosis for whom SAVR is considered suitable and does not pose a high risk, the evidence on the efficacy of TAVR is inadequate. NICE encourages clinicians to enter suitable patients into a clinical trial (NICE, 2012).

The Valve Academic Research Consortium (VARC), an independent collaboration between academic research organizations and specialty societies (cardiology and cardiac surgery) in the United States and Europe, is focused on creating consistent endpoint definitions and consensus recommendations for TAVR. In an effort to improve the quality of clinical research and to enable meaningful comparisons between clinical trials, consensus criteria were developed for the following endpoints: mortality, myocardial infarction, stroke, bleeding, acute kidney injury, vascular complications and prosthetic valve performance. Composite endpoints for safety and effectiveness were also recommended. The consensus document is not intended as a 'guidelines' or 'guidance' document and although thoroughly reviewed by individuals from seven cardiology and cardiac surgery societies, the content has not been subjected to a formal society guidelines review process (Leon et al. 2011). In a subsequent consensus document, Kappetein et al. (2012) provided additional detail on definitions to further standardize endpoint definitions.

Pulmonary Valve

An ECRI emerging technology evidence report states that studies using the Melody system indicate that percutaneous pulmonary valve implantation (PPVI) improves symptoms as indexed by the New York Heart Association Classification system in the short-term (<6 months), but longer-term results are not available. Studies using the Melody system also indicate that PPVI improves cardiac function on several measures (i.e., decreases RVOT pressure gradient, decreases regurgitation fraction through the pulmonary valve, and decreases right ventricular end-diastolic volume; data on maximal oxygen consumption are not consistent). No data were available to assess how PPVI affects quality of life. Ongoing clinical trials should help clarify questions not addressed by the available literature, including quality of life and long-term clinical outcomes (ECRI, 2012c).

A Hayes report concluded that the evidence evaluating PPVI was of very low quality and consisted entirely of observational studies. Sample sizes were small, long-term follow-up was available for very few patients and there was considerable overlap in patient populations. No randomized controlled trials were identified in the literature. The current evidence showed consistent improvement in hemodynamics for patients presenting with pulmonary regurgitation, stenosis, or both, following PPVI. The procedure appears to have a small but measurable positive impact on heart function while pulmonary function did not improve. The small number of studies and design limitations do not allow conclusions as to whether PPVI reduces reintervention rates or disease-related mortality. The report also notes that surgical valve placement is not an ideal control because PPVI is proposed as an adjunct to surgery and not to replace surgery. There are medical and ethical concerns in directly comparing the 2 procedures in a randomized controlled trial which may compromise the quality of evidence in future studies. Although there is very limited evidence at this time, PPVI fills a gap in the management of patients with right ventricular outflow tract (RVOT) dysfunction following surgical repair for congenital heart defects. Although PPVI can cause severe complications, it is a treatment option used for patients who cannot undergo open heart surgery or to prolong the need for surgical valve replacement with its associated risks. There is insufficient evidence to establish definitive patient selection criteria (Hayes, 2013b).

Butera et al. (2013) conducted a prospective, multicenter web-based registry study of percutaneous pulmonary valve implantation (PPVI). Between October 2007 and October 2010, 63 patients were included in the registry (median age: 24 years; range 11-65 years). Results suggest that PPVI has good procedural and mid-term success and might delay surgical intervention in more than 80% of patients. However, serious complications can occur and valve failure occurred in almost 20% of patients during follow-up. The authors concluded that longer follow-up and larger series are needed.

Eiken et al. (2011) reported on a two-center experience with percutaneous pulmonary valve implantation (PPVI) in 102 patients with right ventricular outflow tract (RVOT) dysfunction. Median weight was 63 kg (54.2-75.9 kg). Median age was 21.5 years (16.2-30.1 years). The median peak systolic RVOT gradient decreased from 37 mmHg (29-46 mmHg) to 14 mmHg (9-17 mmHg), and the ratio right ventricular (RV) pressure/aortic pressure (AoP) decreased from 62% (53-76%) to 36% (30-42%). The median end-diastolic RV-volume index decreased from 106 mL/m² (93-133 mL/m²) to 90 mL/m² (71-108 mL/m²). Pulmonary regurgitation was significantly reduced in all patients. One patient died due to compression of the left coronary artery. The incidence of stent fractures was 5 of 102 (5%). During follow-up [median: 352 days (99-390 days)] one percutaneous valve had to be removed surgically 6 months after implantation due to bacterial endocarditis. In 8 of 102 patients, a repeated dilatation of the valve was done due to a significant residual systolic pressure gradient, which resulted in a valve-in-valve procedure in four patients. The authors concluded that percutaneous pulmonary valve implantation can be performed by experienced interventionalists with similar results to previously published studies. The procedure is technically challenging and longer clinical follow-up is needed.

McElhinney et al. (2010) conducted a 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 right ventricular outflow tract gradient was 37 mmHg before implantation and 12 mmHg immediately after implantation. Before implantation, pulmonary regurgitation was moderate or severe in 92 patients. No patient had more than mild pulmonary regurgitation early after implantation or during follow-up. Freedom from stent fracture was 77.8+/-4.3% at 14 months. Freedom from valve dysfunction or reintervention was 93.5+/-2.4% at 1 year. A higher right ventricular outflow tract 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 right ventricular outflow tract obstruction, highlighting the importance of patient selection, adequate relief of obstruction, and measures to prevent and manage stent fracture. (Clinicaltrials.gov number NCT00740870)

Zahn et al. (2009) evaluated the safety, procedural success and short-term effectiveness of the Melody transcatheter pulmonary valve in patients with dysfunctional right ventricular outflow tract conduits. Thirty four patients underwent catheterization for intended Melody valve implantation at 3 centers. Mean age was 19.4 +/- 7.7 years. Initial conduit Doppler mean gradient was 28.8 +/- 10.1 mmHg, and 94% of patients had moderate or severe pulmonary regurgitation (PR). Implantation was successful in 29 of 30 attempts and not attempted in 4 patients. Procedural complications included conduit rupture requiring urgent surgery and device removal (n = 1), wide-complex tachycardia (n = 1) and distal pulmonary artery guidewire perforation (n = 1). Peak systolic conduit gradient fell acutely from 37.2 +/- 16.3 mmHg to 17.3 +/- 7.3 mmHg, and no patient had more than mild PR. There were no deaths or further device explants. At 6-month follow-up, conduit Doppler mean gradient was 22.4 +/- 8.1 mmHg, and PR fraction by magnetic resonance imaging was significantly improved (3.3 +/- 3.6% vs. 27.6 +/- 13.3%). Stent fracture occurred in 8 of 29 implants; 3 of these were treated with a second Melody valve for recurrent stenosis later in follow-up. The authors concluded that implantation of the Melody valve for right ventricular outflow tract conduit dysfunction has encouraging acute and short-term outcomes when performed by experienced operators.

In a retrospective case series, Lurz et al. (2008) evaluated percutaneous pulmonary valve implantation in 155 patients with stenosis and/or regurgitation. The procedure led to significant reduction in right ventricular systolic pressure and right ventricular outflow tract gradient. Follow-up ranged from 0 to 83.7 months (median 28.4 months). Freedom from reoperation was 93% (+/-2%), 86% (+/-3%), 84% (+/-4%) and 70% (+/-13%) at 10, 30, 50 and 70 months, respectively. Freedom from transcatheter reintervention was 95% (+/-2%), 87% (+/-3%), 73% (+/-6%) and 73% (+/-6%) at 10, 30, 50 and 70 months, respectively. Survival at 83 months was 96.9%. The first series of 50 patients and patients with a residual gradient >25 mmHg were associated with a higher risk of reoperation.

In a retrospective case series, Khambadkone et al. (2005) evaluated percutaneous pulmonary valve implantation (PPVI) in 59 patients with pulmonary regurgitation with or without stenosis after repair of congenital heart disease. PPVI was performed successfully in 58 patients (32 male; median age of 16 years and median weight of 56 kg). The right ventricular (RV) pressure, right ventricular outflow tract (RVOT) gradient and pulmonary regurgitation (PR) decreased significantly after percutaneous pulmonary valve implantation. In 28 patients, magnetic resonance imaging showed significant reduction in PR fraction and in RV end-diastolic volume (EDV) and a significant increase in left ventricular EDV and effective RV stroke volume.

A National Institute for Health and Care Excellence (NICE) guidance document states that the evidence on percutaneous pulmonary valve implantation for right ventricular outflow tract (RVOT) dysfunction shows good short-term efficacy. There is little evidence on long-term efficacy but it is

well documented that these valves may need to be replaced in the longer term. With regard to safety there are well-recognized complications, particularly stent fractures in the longer term, which may or may not have clinical effects. Patients having this procedure are often very unwell and might otherwise need open heart surgery (typically reoperative) with its associated risks (NICE, 2013).

Post-approval clinical trials are ongoing to assess the long-term clinical performance of the Melody transcatheter pulmonary valve.

Mitral Valve

Percutaneous Leaflet Repair

Evidence from one large randomized controlled trial suggests that transcatheter mitral valve repair using the MitraClip device is not as effective as conventional surgery for patients who are candidates for conventional surgery. Although patient survival and decrease in MR were similar for the MitraClip procedure versus conventional open surgery at 4 years follow-up, MitraClip implantation was associated with a statistically significant increase in the need for additional surgery. A small number of nonrandomized comparison studies and several uncontrolled studies provide weak evidence that the MitraClip device may be more effective than standard treatment for high-risk patients who are not candidates for conventional surgery. Additional studies are needed to determine the long-term risks versus benefits of MitraClip implantation in these high-risk patients (Hayes, 2014).

EVEREST II (Endovascular Valve Edge-to-Edge Repair Study)

EVEREST II is a two-part multicenter, randomized controlled trial to evaluate the safety and efficacy of endovascular mitral valve repair using the MitraClip device compared with conventional mitral valve surgery in patients with moderate to severe mitral regurgitation (MR). The study is funded by Abbott Vascular. EVEREST II consists of a randomized arm and a high-risk registry arm. (Clinicaltrials.gov number NCT00209274)

EVEREST II Randomized Arm

Feldman et al. (2011) randomly assigned 279 patients with moderately severe or severe (grade 3-4+) MR in a 2:1 ratio to undergo either percutaneous repair (n=184) or conventional surgery (n=95) for repair or replacement of the mitral valve. The patients enrolled in this trial had a normal surgical risk and mainly degenerative MR with preserved left ventricular function. The primary end point for efficacy was freedom from death, from surgery for mitral-valve dysfunction and from grade 3-4+ MR at 12 months. The primary safety end point was a composite of major adverse events within 30 days. At 12 months, the rates of the primary end point for efficacy were 55% in the percutaneous-repair group and 73% in the surgery group. The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3-4+ MR, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients 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 MR than conventional surgery at 12 and 24 months, the procedure was associated with a lower adverse event rate and similar improvements in clinical outcomes.

At 4 years follow-up, Mauri et al. (2013) reported no significant differences between the MitraClip and conventional surgery treatment groups in all-cause mortality, presence of moderate or severe MR or event-free survival. However, at 4 years follow-up, additional mitral valve surgery was needed for 25% of MitraClip patients versus 6% of conventional surgery patients.

EVEREST II High Risk Registry Arm

Whitlow et al. (2012) evaluated 78 high-risk symptomatic patients with severe (Grade 3 or 4+) MR and an estimated surgical mortality rate of $\geq 12\%$. Percutaneous mitral valve leaflet repair, using the MitraClip device, was compared with 36 patients with similar degrees of MR, risks and

comorbidities who were screened for the study but were not enrolled for various reasons. The devices were successfully placed in 96% of patients. Procedure-related mortality rate at 30 days was similar in the patients who underwent MitraClip placement and the comparator group (7.7% versus 8.3%), but the MitraClip patients appeared to have a better 1-year survival (76% versus 55%). In surviving patients with matched baseline and 12-month data, 78% had an MR grade of $\leq 2+$. Left ventricular end-diastolic volume improved from 172 ml to 140 ml, and end-systolic volume improved from 82 ml to 73 ml. New York Heart Association functional class improved from III/IV at baseline in 89% to class I/II in 74%. Quality of life improved (Short Form-36 physical component score increased from 32.1 to 36.1), and the mental component score increased from 45.5 to 48.7 at 12 months. The annual rate of hospitalization for congestive heart failure in surviving patients with matched data decreased from 0.59 to 0.32. The authors concluded that the MitraClip device reduced MR in a majority of patients deemed at high risk of surgery, resulting in improvement in clinical symptoms and significant left ventricular reverse remodeling over 12 months. The study has several limitations, most notably a lack of randomization and a questionable comparator group that was recruited retrospectively.

EVEREST (Endovascular Valve Edge-to-Edge Repair Study)

EVEREST is a multicenter, prospective single-arm study to evaluate the feasibility, safety and efficacy of a percutaneous mitral valve repair system (MitraClip) for treating MR. Patients will undergo 30-day, 6 month, 12 month and 5 year clinical follow-up. The study is funded by Abbott Vascular. (Clinicaltrials.gov number NCT00209339)

Feldman et al. (2009) conducted a prospective, multicenter single-arm study to evaluate the feasibility, safety and efficacy of the MitraClip system. A total of 107 patients with moderate to severe (grade 3-4+) MR or compromised left ventricular function (if asymptomatic) underwent percutaneous valve repair with the MitraClip device. Ten (9%) had a major adverse event, including 1 nonprocedural death. Freedom from clip embolization was 100%. Partial clip detachment occurred in 10 (9%) patients. Overall, 74% of patients achieved acute success and 64% were discharged with MR of $\leq 1+$. Thirty-two patients (30%) had mitral valve surgery during the 3.2 years after clip procedures. When repair was planned, 84% (21 of 25) were successful. Thus, surgical options were preserved. A total of 50 of 76 (66%) successfully treated patients were free from death, mitral valve surgery or MR $> 2+$ at 12 months (primary efficacy end point). Kaplan-Meier freedom from death was 95.9%, 94.0% and 90.1%, and Kaplan-Meier freedom from surgery was 88.5%, 83.2% and 76.3% at 1, 2 and 3 years, respectively.

Maisano et al. (2013) and Reichenspurner et al. (2013) reported early outcomes from the ACCESS-EU trial. The prospective, multicenter, nonrandomized post-approval study enrolled 567 patients with MR. Maisano et al. reported an implant success rate of 99.6%. Nineteen patients (3.4%) died within 30 days after the MitraClip procedure. Survival at 1 year was 81.8%. Thirty-six patients (6.3%) required mitral valve surgery within 12 months after the implant procedure. There was improvement in the severity of MR at 12 months, compared with baseline. In a subset of 117 patients with severe degenerative MR, Reichenspurner et al. reported that the MitraClip procedure resulted in significant reductions in MR and improvements in clinical outcomes at 12 months. Limitations of this study include lack of randomization, absence of a control group and short-term follow-up. Additionally, patient selection criteria varied at participating centers.

Cohort studies have compared the MitraClip procedure in high-risk patients with conventional surgery in patients at normal risk. The largest of these studies enrolled 171 patients with secondary MR and found that after 6 months, the MitraClip procedure was associated with lower survival (87% versus 96% of patients) and lower freedom from moderate or severe MR (88% versus 97% of patients). These differences may have been due to the poorer health status of patients who underwent the MitraClip procedure. Adjustment for these differences eliminated the statistically significant difference in survival (Conradi et al., 2013). Similar results were obtained by Taramasso et al. (2012) in a cohort study that enrolled 143 patients and preferentially assigned higher-risk patients to the MitraClip procedure. At 1-year follow-up, there were no significant differences between the treatment groups in patient survival but the MitraClip group

was more likely to have moderate or severe MR (21% versus 6% of patients). Again, these differences may have been due to the poorer health status of patients who underwent the MitraClip procedure.

A National Institute for Health and Care Excellence (NICE) guidance document states that the evidence on the safety and efficacy of percutaneous mitral valve leaflet repair for MR is currently inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for patients who are well enough for surgical mitral valve repair or in the context of research for patients who are not well enough for surgical mitral valve repair (NICE, 2009).

Several clinical trials are ongoing.

Percutaneous Annuloplasty

A Hayes report concluded that there is insufficient evidence to evaluate the Carillon procedure for percutaneous mitral valve repair (Hayes, 2014).

Siminiak et al. (2012) evaluated whether percutaneous mitral annuloplasty (Carillon Mitral Contour System) could safely and effectively reduce functional mitral regurgitation (FMR) and yield durable long-term clinical benefit. Patients in whom the device was placed then acutely recaptured for clinical reasons served as a comparator group. Quantitative measures of FMR, left ventricular (LV) dimensions, New York Heart Association (NYHA) class, 6 min walk distance (6MWD), and quality of life were assessed in both groups up to 12 months. Safety and key functional data were assessed in the implanted cohort up to 24 months. Thirty-six patients received a permanent implant; 17 had the device recaptured. The 30-day major adverse event rate was 1.9%. In contrast to the comparison group, the implanted cohort demonstrated significant reductions in FMR as represented by regurgitant volume. There was a corresponding reduction in LV diastolic volume and systolic volume compared with progressive LV dilation in the comparator. The 6MWD markedly improved for the implanted patients by 102.5 ± 164 m at 12 months and 131.9 ± 80 m at 24 months. The authors concluded that percutaneous reduction of FMR using a coronary sinus approach is associated with reverse LV remodelling. Significant clinical improvements persisted up to 24 months. While this study provides a comparator group with which to evaluate the hemodynamic and clinical significance of treating FMR, the lack of a randomized and blinded comparator also remains the primary limitation of the study. According to the authors, a randomized trial comparing intervention with a medically managed control group is warranted.

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, New York Heart Association 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.

A National Institute for Health and Care Excellence (NICE) guidance document states that the current evidence on the safety and efficacy of percutaneous mitral valve annuloplasty is inadequate in quality and quantity. Therefore this procedure should only be used in the context of

research, which should clearly describe patient selection, concomitant medical therapies and safety outcomes. Both objective measurements and clinical outcomes should be reported (NICE, 2010).

Professional Societies

American College of Cardiology (ACC)/Society of Thoracic Surgeons (STS)

ACC guidelines for the management of patients with valvular heart disease (Nishimura et al., 2014) make the following recommendations regarding transcatheter valve replacement:

Aortic

- Transcatheter aortic valve replacement (TAVR) is recommended in patients who meet an indication for aortic valve replacement (AVR) for aortic stenosis who have a prohibitive surgical risk and a predicted post-TAVR survival >12 mo. (Class I recommendation, level of evidence B – procedure is useful/effective based on evidence from a single randomized trial or nonrandomized studies.)
- TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR and who have high surgical risk. (Class IIa recommendation, level of evidence B – procedure is reasonable but based on conflicting evidence from a single randomized trial or nonrandomized studies.)
- TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of aortic stenosis. Class III: no benefit, level of evidence B – procedure has no proven benefit based on evidence from a single randomized trial or nonrandomized studies.)
- For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care. (Class I recommendation, level of evidence C - based on expert opinion, case studies or standard of care.)

Mitral

Transcatheter mitral valve repair may be considered for severely symptomatic patients (New York Heart Association 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 guideline-directed medical therapy for heart failure. (Class IIb recommendation, level of evidence B - procedure may be considered but usefulness/efficacy is less well established based on conflicting evidence from a single randomized trial or nonrandomized studies.)

Pulmonary

Transcatheter pulmonary valve replacement is outside the scope of these guidelines. See Warnes et al., 2008.

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 requirements for creating and maintaining transcatheter aortic valve replacement programs. The recommendations are aimed at ensuring optimal patient care (Tommaso et al., 2012). The same organizations released a similar statement addressing transcatheter therapies for MR (O’Gara et al., 2013).

In a separate publication, these organizations provide additional expert consensus recommendations for patient selection, screening and post-procedural care. These recommendations specify that TAVR is recommended for adults with severe, symptomatic, calcific stenosis of a trileaflet aortic valve who have aortic and vascular anatomy suitable for TAVR and a predicted survival of 12 months. TAVR is recommended in patients with prohibitive

surgical risk and is a reasonable alternative to SAVR in patients at high surgical risk. Prohibitive surgical risk is defined by an estimated $\geq 50\%$ risk of mortality or irreversible morbidity at 30 days or other factors such as frailty, prior radiation therapy, porcelain aorta and severe hepatic or pulmonary disease (Holmes et al., 2012).

In a joint consensus document, ACC and STS state that transcatheter valve therapy is a transformational technology with the potential to significantly impact the clinical management of patients with valvular heart disease in a less invasive manner. Although the initial experience is positive, evidence exists from only 1 randomized clinical trial in patients with aortic stenosis and 1 in patients with mitral insufficiency. Adoption of these techniques to populations beyond those studied in these randomized trials, therefore, is not appropriate at the current time. However, in view of the promising results obtained in these limited population subsets, conduct of further randomized trials in other patient groups is strongly encouraged.

Both ACC and STS strongly recommend the use of a “heart team” approach in which both a cardiothoracic surgeon and a cardiologist actively participate in the procedure. The consensus document makes recommendations for populating the heart team.

Participation in a national registry is also strongly recommended. The STS/ACCF TVT Registry is now enrolling participant sites (<https://www.ncdr.com/TVT/Home/Default.aspx>). Data from this registry will provide clinical short-term and long-term follow-up information necessary to monitor outcomes as well as quality-of-life. The registry will also provide information that can be used to assess appropriateness of care as well as overuse (Holmes and Mack, 2011).

ACC guidelines on the management of adults with congenital heart disease address percutaneous therapies for reintervention in patients with right ventricular outflow tract dysfunction. Therapies include balloon dilation, stenting or percutaneous valve replacement. While promising, percutaneous valve replacement is considered investigational as it has yet to be proven in larger clinical trials (Warnes et al., 2008).

American Heart Association (AHA)

In a scientific statement, the AHA states that percutaneous valve therapy devices and techniques require significant changes before widespread clinical use is possible. Randomized comparisons with existing standard of care treatments and registries for high-risk patients will define the roles of these new technologies. For the near term, percutaneous techniques will likely remain investigational and will be limited in use to patients considered to be high risk or to inoperable surgical candidates. Even after FDA approvals, percutaneous devices should be used in only a small number of centers with excellent surgical and catheter experience until they are thoroughly tested in the clinical arena. The AHA also states that less invasive and percutaneous valve therapies will likely have a major impact on the management of patients with valvular heart disease over the next several years (Rosengart et al., 2008).

An AHA scientific statement on interventions for pediatric cardiac disease concluded that it is reasonable to consider percutaneous pulmonary valve replacement in a patient with a right ventricular-pulmonary artery conduit with associated moderate to severe pulmonary regurgitation or stenosis provided the patient meets inclusion/exclusion criteria for the available valve (Feltes et al., 2011). (Class IIa recommendation, level of evidence B – although there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of procedure, weight of evidence/opinion is in favor of usefulness/efficacy based on data derived from a single randomized trial or nonrandomized studies.)

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

EACTS and ESC guidelines on the management of valvular heart disease make the following recommendations regarding TAVR:

- TAVR should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.
- TAVR should only be performed in hospitals with cardiac surgery on-site.
- TAVR is indicated in patients with severe symptomatic aortic stenosis who are not suitable for aortic valve replacement as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.
- TAVR should be considered in high-risk patients with severe symptomatic aortic stenosis who may still be suitable for surgery, but in whom TAVR is favored by a 'heart team' based on the individual risk profile and anatomic suitability.

The guidelines also address percutaneous edge-to-edge repair for patients with primary MR. The EVEREST trials and other studies suggest that percutaneous edge-to-edge mitral valve repair is relatively safe, usually well tolerated even by patients in poor clinical condition and has a success rate of approximately 75%. Despite these benefits, percutaneous mitral valve repair does not reduce MR as effectively as mitral valve surgery. The guidelines caution that valve replacement may be necessary in up to 50% of patients who have unsuccessful clip implantation. Experience from a limited number of patients suggests that percutaneous edge-to-edge mitral valve repair is feasible in patients with secondary or functional MR. The procedure may provide short-term improvement in functional condition and LV function. These findings have to be confirmed in larger series with longer follow-up and with a randomized design.

The guidelines only briefly mention that data on coronary sinus annuloplasty is limited (Vahanian et al., 2012).

EACTS and ESC, in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI), published a position statement on transcatheter valve implantation for patients with aortic stenosis. The document states that currently available results obtained with TAVR suggest that these techniques are feasible and provide hemodynamic and clinical improvement for up to 2 years in patients with severe symptomatic aortic stenosis at high risk or with contraindications for surgery. Pending questions concern safety and long-term durability. A careful commercialization process, including training and post-market surveillance, is crucial to avoid the risk of uncontrolled diffusion. The group acknowledges that the conclusions rely on limited data reported mostly in oral communications and few in peer-reviewed journals (Vahanian et al., 2008).

European Society of Cardiology (ESC)

ESC guidelines for the management of adult congenital heart disease state that the decision to perform a percutaneous pulmonary valve implantation should involve a process of rigorous peer review and multidisciplinary discussion, as currently few data exist to demonstrate non-inferiority over surgery for many of these approaches. Mid-/long-term outcome data are not available yet for this procedure. Surgery is preferred over percutaneous methods when additional interventions are being considered (Baumgartner et al., 2010).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Aortic

The Edwards SAPIEN Transcatheter Heart Valve received FDA premarket approval (P100041) on November 2, 2011. The device is indicated for transfemoral delivery in patients with severe, symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis. The device is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who

have active bacterial endocarditis or other active infections. Labeling also states that implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon aortic valvuloplasty. Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P100041>

Accessed April 18, 2014.

On October 19, 2012, the FDA approved an expanded indication for the Edwards SAPIEN valve to include patients with aortic stenosis who are eligible for surgery but who are at high risk for serious surgical complications or death (P110021). In this patient group, the valve is approved for both transfemoral and transapical delivery.

Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p110021>

Accessed April 18, 2014.

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

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

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

Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P130021>

Accessed April 18, 2014.

On February 12, 2013, the FDA granted the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) a unique investigational device exemption (IDE) to study "alternative access" approaches for transcatheter aortic valve replacement (TAVR) using the STS/ACC TVT Registry™. Currently, only the transfemoral approach to TAVR using the Edwards SAPIEN valve has been approved for inoperable patients. Both the transfemoral and transapical approaches have been approved for high risk patients. An estimated 1 in 4 patients is ineligible for these procedures because of inadequate vessel size, vessel disease or other considerations. The new STS/ACC study protocol, as approved by CMS, allows Medicare reimbursement for alternative access to the aortic valve via the heart muscle or the aorta (transaortic approach) in inoperable patients involved in the study. The goal of the study is controlled off-label use of an approved device (STS press release, 2013). Available at: <http://www.sts.org/news/sts-acc-receive-fda-approval-ide-study-alternative-access-tavr>. Accessed April 18, 2014.

Pulmonary

The Medtronic Melody Transcatheter Pulmonary Valve and Ensemble Delivery System received FDA approval under the Humanitarian Device Exemption (HDE) program on January 25, 2010 (H080002). A HDE application is similar to a premarket approval (PMA) application, but is exempt from the effectiveness requirements. FDA approval of an HDE grants limited marketing approval for a Humanitarian Use Device (HUD). A HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year.

The Melody transcatheter pulmonary valve is approved for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) dysfunctional right ventricular outflow tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted AND
- Dysfunctional RVOT conduit with a clinical indication for intervention, and either:
 - Regurgitation: \geq moderate regurgitation OR
 - Stenosis: mean RVOT gradient \geq 35 mmHg

Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=H080002>.

Accessed April 10, 2014.

Mitral

The MitraClip Mitral Valve Repair System received FDA premarket approval (P100009) on October 24, 2013. The device is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR \geq 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation. Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=P100009>.

Accessed April 11, 2014.

Additional Products

Carillon® Mitral Contour System™ for percutaneous annuloplasty – not FDA approved

Portico™ (St. Jude Medical) – not FDA approved

SAPIEN XT (Edwards Lifesciences) – not FDA approved

SAPIEN pulmonary valve (Edwards Lifesciences) – not FDA approved

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers transcatheter aortic valve replacement (TAVR) when criteria are met. See the National Coverage Determination (NCD) for [Transcatheter Aortic Valve Replacement \(TAVR\) \(20.32\)](#). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have an NCD for transcatheter pulmonary heart valve replacement. There are LCDs which address implantation of catheter-delivered prosthetic pulmonary valve (CPT code 0262T). Refer to the LCDs for [Category III CPT Codes, Non Covered Services, Non-Covered Category III CPT Codes](#), and [Services That Are Not Reasonable and Necessary](#).

Medicare does not have an NCD for transcatheter mitral valve leaflet repair and percutaneous mitral valve annuloplasty. There are Local Coverage Determinations (LCDs) which address transcatheter mitral valve repair (CPT codes 0343T, 0344T and 0345T). See the LCDs [Non-Covered Category III CPT Codes](#), and [Services That Are Not Reasonable and Necessary](#). Local

Articles exist which address coverage for MitraClip® Percutaneous Mitral Valve Repair System. See the Noridian Local Article for [MitraClip® Percutaneous MITRAL Valve Repair System](#).

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
07/01/2014	<ul style="list-style-type: none">• Reorganized policy content• Updated benefit considerations; added language for <i>Essential Health Benefits for Individual and Small Group</i> plans to indicate:<ul style="list-style-type: none">○ For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-

Date	Action/Description
	<p>grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)</p> <ul style="list-style-type: none"> ○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans ○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage ● Updated coverage rationale: <ul style="list-style-type: none"> ○ Added language to indicate if service is “medically necessary” or “not medically necessary” to applicable proven/unproven statement ○ Removed references to specific product/device names ● Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references ● Archived previous policy version 2014T0557E