Anthem

Medical Policy

Subject: Transcatheter Heart Valve Procedures
Document #: SURG.00121
Status: Revised
Publish Date: 05/25/2023
Last Review Date: 05/11/2023

Description/Scope

This document addresses the transcatheter (percutaneous or catheter-based) approach for aortic or pulmonary heart valve replacement, transcatheter edge-to-edge repair (also referred to as 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 the following criteria have been met:

A. The individual has severe degenerative, native valve aortic stenosis demonstrated by **one** of the following:
   1. The aortic valve area (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. 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. *Age 65 years or older with* **any open surgical risk**; **or**
   2. *Age younger than 65 with* **intermediate or greater open surgical risk** (predicted risk of surgical mortality at 30 days greater than or equal to 3%) as determined by at least two physicians.

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 Mitral Edge-to-Edge Repair:

Transcatheter mitral edge-to-edge repair/transcatheter mitral valve repair using an FDA approved device** is considered **medically necessary** when individual has **one** of the following conditions:

A. ***Chronic degenerative (primary) mitral regurgitation*** (***MR)*** and meets **all** the following criteria;
   1. Graded as moderate-to severe (3+ to 4+) MR; **and**
   2. Severely symptomatic heart failure (NYHA class III or IV); **and**
   3. Echocardiogram demonstrates that the primary regurgitant jet results from malcoaptation of the A2 and P2 scallops of the mitral valve; **and**
   4. Prohibitive surgical risk for open surgical therapy (predicted risk of surgical mortality greater than or equal to 8% at 30 days) as determined by at least two physicians (Multidisciplinary Heart valve team);
      or
B. ***Functional (secondary) MR*** and meets **all** the following criteria:
   1. Graded as moderate-severe (3+ to 4+) MR; **and**
   2. Severely symptomatic heart failure (NYHA class III or IV); **and**
   3. Echocardiogram demonstrates that the primary regurgitant jet results from malcoaptation of the A2 and P2 scallops of the mitral valve; **and**
   4. MR severity persist despite maximally tolerated guideline-directed medical therapy as determined by at least two physicians (Multidisciplinary Heart Team).

****Note:** Please refer to background section of document for list of FDA approved transcatheter mitral valve repair devices.

Transcatheter Pulmonary Valve (TPV):

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

A. Dysfunctional right ventricular outflow tract (RVOT) tract (native, patched or implanted conduit) 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.

Transcatheter mitral edge-to-edge repair/transcatheter mitral valve repair is considered **not medically necessary** for the treatment of primary or secondary (functional) MR when the criteria above are not met.

Investigational and Not Medically Necessary:

TAVR cerebral protection devices (for example, Sentinel™ Cerebral Protection System) are considered **investigational and not medically necessary** for all indications.

Transcatheter mitral edge-to-edge repair/transcatheter mitral valve repair is considered **investigational and not medically necessary** for all other indications.

Valve-in-valve transcatheter mitral valve replacement 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

The Centers for Disease Control and Prevention (CDC) estimates that about 2.5% of the U.S. population has valvular heart disease. The prevalence of valvular heart disease increases with age and affects about 13% of people born before 1943, when penicillin became widely available to treat streptococcal infection and thereby prevent development of rheumatic heart disease. There are about 28,000 deaths due to valvular heart disease each year in the U.S.; approximately 61% of these deaths are due to aortic valve disease, 15% from mitral valve disease, and 24% to dysfunction in the pulmonary or tricuspid valves (CDC, 2019).

The 2020 American College of Cardiology (ACC)/ American Heart Association (AHA) Guideline for the Management of individuals with valvular heart disease notes that the severity of valvular heart disease is characterized based on symptoms, valve anatomy, the severity of valve dysfunction, and the response of the ventricle and pulmonary circulation.

Prior to the 1980s, the only surgical options for individuals with severe symptomatic valvular heart disease who received inadequate benefits from medical therapy were open heart procedures. Many of the candidates for these procedures had prohibitive surgical risk due to the severity of their disease. Beginning with percutaneous pulmonary valvuloplasty in 1982, a variety of transcatheter valve interventions have been developed for each of the heart valves.

Transcatheter Aortic Valve Replacement (TAVR):

Techniques and technologies for TAVR have evolved significantly since the original proof of concept reported by Cribner in 2002. TAVR was initially considered an option only for otherwise inoperable individuals over conventional surgical aortic valve replacement (SAVR). Proposed indications for transcatheter aortic valve replacement have expanded for selected individuals with lower surgical risk as more experience has been gained with this procedure. TAVR is sometimes labeled as transcatheter aortic valve implantation (TAVI). In this document we consider TAVR and TAVI to be equivalent terms and will refer to the procedure as TAVR.

The design and major outcomes of major clinical trials investigating TAVR are summarized below:

Study	**Rode's-Cabau 2010/2012**	**PARTNER B 2010/2015**	**PARTNER A 2011**	**CoreValve 2014/2018**	**PARTNER 2 2016/2020**	**SURTAVI 2017/2022**	**PARTNER 3 2019/2021**	**EVOLUT 2019**
Lead Author	Rodes-Cabau	Leon Kapadia	Smith	Adams Gleason	Mack Makkar	Reardon Van Mieghem	Mack Leon	Popma
Design	Case series	RCT **TAVR vs Standard Care**	RCT **TAVR vs SAVR**	RCT **TAVR vs SAVR**	RCT **TAVR vs SAVR**	RCT **TAVR vs SAVR**	RCT **TAVR vs SAVR**	RCT **TAVR vs SAVR**
Device	SAPIEN or SAPIEN XT	SAPEIN	SAPIEN	CoreValve	SAPIEN XT or SAPIEN 3	CoreValve	SAPIEN 3	CoreValve, Evolut R, or Evolut Pro
Risk Level	High or prohibitive	Inoperable	High	High	Intermediate	Intermediate	Low	Low
N	345	358	699	795	2032	1746	1000	1403
Duration (# completing)	42 ± 15 months	1year (358) 5year (55)	1 year (699)	1 year (747) 5 year (158)	2 year (2032) 5 year (1751)	24 months (1660) 5 year (929)	1 year (984)	24 months (921)
Mortality (%):								
• 30 day	10.4	5.0 vs 2.8	3.4 vs 6.5	3.3 vs 4.5	3.9 vs 4.1	2.2 vs 1.7	0.4 vs 1.1	0.5 vs 1.3
• 1 year	26	24.3 vs 26.8	24.2 vs 26.8	14.2 vs 19.1	12.3 vs 12.9	6.7 vs 6.8	1.0 vs 2.5	2.4 vs 3.0
• 2 year					16.7 vs 18.0	11.4 vs 11.6	2.5 vs 3.2	4.5 vs 4.5
• 5 year	55 at 42±15 months	33.9 TAVR		55.3 vs 55.4	47.9 vs 43.4	30 vs 28.7		
Repeat hospitalization								
• 30 day		5.6 vs 10.6	4.4 vs 3.7			2.9 vs 4.2	3.4 vs 6.5	1.2 vs 2.5

Study	Rode's-Cabau 2010/2012	PARTNER B 2010/2015	PARTNER A 2011	CoreValve 2014/2018	PARTNER 2 2016/2020	SURTAVI 2017/2022	PARTNER 3 2019/2021	EVOLUT 2019
• 1 year		22.3 vs 44.1	18.2 vs 15.5			8.5 vs 7.6	7.3 vs 11.0	3.2 vs 6.5
• 2 year					19.9 vs 17.5	13.2 vs 9.7	8.5 vs 12.5	
• 5 year						23.9 vs 20.8		
Stroke or TIA								
• 30 day		6.7 vs 1.7	5.5 vs 2.4	4.9 vs 6.2	5.5 vs 4.3	4.5 vs 6.5	0.6 vs 2.4	3.4* vs 3.4*
• 1 year		10.6 vs 4.5	8.3 vs 4.3	8.8 vs 12.6	8.0 vs 5.8	8.2 vs 8.6	1.2 vs 3.3	4.1 vs 4.3
• 2 year					9.5 vs 6.4	10.0 vs 11.0	2.5 vs 3.6	
• 5 year				17.5 vs 21.0		11.6 vs 13.6		
Major Vascular Complications								
• 30 day		30.7 vs 5.0	11.0 vs 3.2	5.9 vs 1.7	7.9 vs 5.0	6.0 vs 1.1	2.2 vs 1.5	3.8 vs 3.2
• 1 year		32.4 vs 7.3	11.3 vs 3.5	6.2 vs 2.0	8.4 vs 5.3		2.8 vs 1.5	3.8 vs 3.5
• 2 year					8.6 vs 5.5			
Major Bleeding								
• 30 day		16.8 vs 3.9	16.8 vs 19.5	28.1 vs 34.5	10.4 vs 43.4	12.2 vs 9.3	3.6 vs 24.5	2.4 vs 7.5
• 1 year		22.3 vs 11.2	17.7 vs 25.7	29.5 vs 36.7	15.2 vs 45.5		7.7 vs 25.9	3.2 vs 8.9
• 2 year					17.3 vs 47.0			
New AF								
• 30 day		0.6 vs 1.1	8.6 vs 16.0	11.7 vs 30.5	9.1 vs 26.4	12.9 vs 43.4	5.0 vs 39.5	7.7 vs 35.4
• 1 year		0.6 vs 1.7	12.1 vs 17.1	15.9 vs 32.7	10.1 vs 27.2		7.0 vs 40.9	9.8 vs 38.3
• 2 year					11.3 vs 27.3			

Outcomes are reported as TAVR vs. SAVR, respectively

A multicenter case series evaluated the outcomes of 345 TAVR procedures in 339 participants who presented with severe symptomatic aortic stenosis (AS) at very high or prohibitive surgical risk (Rodés-Cabau, 2010). The transfemoral [TF] approach was used in 168 and a transapical [TA] approach was used for 177. 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. This study demonstrated the feasibility of transcatheter valve replacement for individuals with extremely high risk of death from an open surgical replacement. It did not, however, compare TAVR to optimal medical management.

Leon and colleagues reported results of the PARTNER clinical trial in 2010. Cohort B of this study evaluated the safety and effectiveness of Edwards SAPIEN THV in a population of inoperable subjects. Subjects in Cohort B were randomized to treatment with TF TAVR or to standard therapy. There were 179 participants in each group. Individuals who did not have suitable femoral access were not enrolled. All enrolled subjects had severe symptomatic AS with a functional NYHA class II or greater. Severe 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. At least two cardiovascular surgeon investigators had to agree that the individual was not a suitable candidate for surgery due to a predicted probability of 50% or more of either death within 30 days after surgery or a serious irreversible complication. Researchers categorized most subjects as high risk based on Society of Thoracic Surgeons (STS) score (average 11 ± 6%). Some subjects had lower STS scores but had pre-existing conditions that contributed to the surgeon's rationale for deeming a participant ineligible for surgery.

There were 9 deaths (5.0%) in the TAVR group within 30 days of their procedure. In the standard care cohort, there were 5 deaths (2.8%) in the first 30 days after randomization. After 12 months, there were 55 deaths (30.7%) in the TAVR group compared to 89 deaths (49.7%) in the standard care group. After 1 year, subjects treated with TAVR were more likely than those in standard care to have experienced a stroke (10.6% TAVR vs 4.5% standard care), vascular complication (32.4% vs 7.3%), or major bleeding episode (22.3% vs 11.2%). Subjects receiving standard care were more likely than those who received TAVR to have required repeat hospitalization (70.4% in standard care vs 42.5% in TAVR), balloon aortic valvuloplasty (36.9 % vs 0.6%), or open aortic valve replacement (9.5% vs 1.1%).

The PARTNER trial provided more evidence of the feasibility of TAVR for severe symptomatic aortic stenosis. While showing

significantly lower 12-month rates of death or need for rehospitalization, TAVR, however, resulted in a markedly higher rate of stroke. The authors proposed that this could be due to the large diameter devices then in use and with the fact that TAVR was a new procedure with which many of the investigators needed to gain experience. An important limitation of the trial was its exclusion of individuals with significant coronary or peripheral vascular disease. Many individuals with severe symptomatic AS also have those conditions.

In 2011, based in part on the results of PARTNER, the Food and Drug Administration (FDA) approved use of the Edwards Sapien Valve for individuals with severe calcific AS who were considered to be non-operable for conventional open-heart valve replacement surgery.

Smith and colleagues (2011) reported results from cohort A of the PARTNER trial in 2011. Cohort A included 699 individuals considered to be at high risk for mortality or severe event following SAVR. Subjects were randomized to receive TAVR or SAVR. The mortality rate (24.2% for TAVR vs. 26.8% for SAVR) and the rate of rehospitalization (18.2% TAVR vs 15.5% SAVR) were comparable 1 year after the procedure. As observed for cohort B, the TAVR arm had higher rates of stroke (8.3% TAVR vs 4.3% SAVR) and vascular complications (18.0% TAVR vs 4.8% SAVR).

The FDA expanded its indications for TAVR in 2012 to include individuals 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.

In 2016, the FDA expanded indications for the SAPIEN XT and SAPIEN 3 transcatheter heart valves to treatment of individuals with symptomatic severe calcific AS at intermediate or greater risk for open surgical therapy. This level of risk was defined as predicted risk of surgical mortality greater than or equal to 3% at 30 days as determined by at least two physicians.

The FDA approval for the SAPIEN XT and SAPIEN 3 devices was based on results from the PARTNER 2 trials. These were two parallel, prospective, multicenter, randomized trials that enrolled 2032 individuals with severe AS at intermediate surgical risk (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. In contrast to the PARTNER trials, PARTNER 2 allowed enrolment of individuals with noncomplex coronary artery disease requiring revascularization. In the SAVR arm, 77 of 1021 participants (7.5%) declined to undergo their assigned procedure. This compares to 17 of 1011 participants (1.7%) declining their procedure in the TAVR arm.

PARTNER 2 found comparable outcomes for TAVR and SAVR. After 2 years, the composite outcome of death from any cause or disabling stroke was 19.3% for TAVR and 21.1% for SAVR. TAVR resulted in larger aortic-valve areas and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation. SAVR resulted in fewer major vascular complications and less paravalvular aortic regurgitation. Major vascular complications occurred in 8.6% of those receiving TAVR as compared to 5.5% of those receiving SAVR. SAVR was more likely to result in life-threatening or disabling bleeding (47.0% vs 17.3%). The SAVR group also had a higher rate of new atrial fibrillation (27.3% vs 11.3%).

The authors of the PARTNER 2 trial concluded that TAVR, when performed by experienced centers using newer valve systems, was shown to be non-inferior to SAVR with regard to mortality or stroke. They also remarked that longer-term study was needed to evaluate the durability of outcomes for this procedure.

In 2020, Makkar and colleagues reported longer-term clinical outcomes after TAVR versus SAVR in the intermediate-risk population (PARTNER 2). 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.”

Mack and colleagues reported preliminary results from the PARTNER 3 trial in 2019. This was a prospective, randomized, controlled, multicenter study evaluating the safety and effectiveness of the SAPIEN 3 transcatheter valve. The study compared TAVR to SAVR in individuals with severe symptomatic AS who were at low risk (STS < 4%) for surgery. The mean age of participants was 73. The mean STS score was 1.9. Investigators randomized 1000 participants into two groups: 496 received TAVR and 465 received SAVR. After 1 year, the composite rate of death, stroke, or hospitalization was 8.5% for the TAVR group and 15.1% in the SAVR group ($p<0.0001$ for non-inferiority). As in PARTNER 2, a much larger number of participants in the SAVR arm declined their procedure (43 of 497 [8.7%] in the SAVR group vs 7 of 503 [1.4%] in the TAVR group). The authors planned a randomized subtrial in which 435 would receive serial CT angiography to evaluate valve leaflet function and possible asymptomatic valve thrombosis.

Popma and colleagues (2019) reported results from a pre-market, multicenter, international, prospective study evaluating TAVR with the Medtronic CoreValve Evolut THV systems to SAVR in individuals with severe AS (AVA of 1.0 cm^2 or less; AVA index of ≤ 0.6 cm^2 per square meter; 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 (STS score ≤ 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 concluded that TAVR was noninferior to SAVR with respect to death from any cause or disabling stroke at 2 years for participants in this trial. They also stated that “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 December 2020, the ACC and AHA published an updated guideline for the management of valvular heart disease in adults (Otto, 2020). The panel offered recommendations for the choice between SAVR or TAVR 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 transfemoral TAVR, either SAVR or transfemoral TAVR 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 TAVR, transfemoral TAVR is recommended in preference to SAVR (*Category 1A*)

Available data beyond 5 years in symptomatic individuals with severe AS who have undergone TAVR 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 the Medtronic Evolut Transcatheter Aortic Valve Replacement trials in low-risk individuals discussed above. (Mack, 2019; Popma, 2019)

In 2021, Leon and colleagues reported follow-up results from the PARTNER 3 (Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low-risk Patients with Aortic Stenosis) in individuals with symptomatic AS, comparing TAVR to SAVR. At 2 years, the primary composite endpoint was reached in 11.5% of participants in the TAVR group vs. 17.4% in the SAVR group.

Mortality, strokes, TIAs, and rehospitalizations each occurred less frequently in the TAVR group than in the SAVR group. The authors noted concern about the possibility that valves inserted by TAVR might not be as durable as valves inserted by SAVR, but noted that 5 year data from use of these valves in PARTNER 2 has not shown a difference in valve durability between the two arms of that trial.

The PARTNER 3 trial provides reassuring evidence that TAVR results in health outcomes comparable to SAVR 2 years after the procedure. The 2020 ACC/AHA guideline (Otto, 2020) notes that TAVR:

> has a slightly lower mortality risk and is associated with a shorter hospital length of stay, more rapid return to normal activities, lower risk of transient or permanent atrial fibrillation, less bleeding, and less pain than SAVR. On the other hand, SAVR is associated with a lower risk of paravalvular leak, less need for valve reintervention, and less need for a permanent pacemaker.

These considerations form the basis for the ACC/AHA guideline 1A recommendation for either SAVR or transfemoral TAVR for individuals at low open surgical risk between the ages of 65-80 based on shared decision making about the balance between patient longevity and valve durability.

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 300 participants, 200 low-risk participants (up to 100 TAVR in bicuspid AS) with expected results in January 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 the 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.

TAVR Embolic Protection Device

In 2022, Kapadia and colleagues conducted a randomized controlled trial (RCT) to assess the safety and efficacy of a cerebral embolic protection device (Sentinel Cerebral Protection System; FDA cleared in 2020) in individuals with aortic stenosis undergoing TAVR. The device consists of two filters placed percutaneously from the right radial or brachial artery in the brachiocephalic artery (proximal filter) and the left common carotid artery (distal filter) before TAVR. The device is removed once TAVR is complete. The study’s primary outcome was stroke within 72 hours of TAVR or prior to discharge. Secondary outcomes included disabling stroke, all-cause mortality, TIA, delirium, and acute kidney injury. In total, 3000 participants were randomized 1:1 to receive the embolic protection device (n=1406, successfully implanted [94% of those attempted]) and 1499 to the control group. The incidence of stroke during the follow-up period did not differ significantly between the intervention and control arms (2.3% vs. 2.9%; p=0.30). The study also did not demonstrate a significant difference between the intervention arm and the control arm in mortality, stroke, TIA, delirium, or acute kidney injury. One vascular complication was reported at the cerebral embolic protection device access site. This RCT did not demonstrate added clinical benefit from implantation of a cerebral embolic protection device in the first 72 hours following TAVR.

Transcatheter Pulmonary Valve (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.

Native or Patched RVOT

There are currently three valves FDA approved for implantation in a native and/or patched RVOT (nonconduit): SAPIEN 3 with the Alterra present, Melody TPV (in a bioprosthetic valve) and the Harmony TPV System.

The European Society Guidelines (2020) state the following:

> TPVI techniques have become an alternative to open heart surgery primarily in patients with RVOT conduit stenosis/regurgitation, but also in selected patients with native RVOT regurgitation/stenosis. TPVI, when technically feasible, provides outcomes comparable to surgical PVRep [pulmonary valve repair] and is intended to extend the lifetime of a conduit, hence reducing the number of reoperations during a patient's lifetime.

And include this recommendation regarding pulmonary valve replacement:

> PVRep should be considered in asymptomatic patients with severe PR and/or RVOTO when one of the following criteria is present. • Decrease in objective exercise capacity. • Progressive RV dilation to RVESVi >_80 mL/m2 , and/or RVEDVi >_160 mL/m2 f, and/or progression of TR to at least moderate. • Progressive RV systolic dysfunction. • RVOTO with RVSP >80 mmHg (Class IIa Level C Recommendation)

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 Edge-to Edge 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 participants (74%) 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.

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. There were 19 deaths within 30 days after the procedure in participants who underwent MitraClip implantation. 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 limited 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 1 year after 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.

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.

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.”

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. 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.” In 2023, 5-year follow-up data from this trial were published. The annualized rate of hospitalization for heart failure narrowed slightly but remained significantly different from the 2-year data at 33.1% per year in the device group and 57.2% per year in the control group (HR, 0.53; 95% CI, 0.41 to 0.68). All-cause mortality remained significantly lower, at 57.3% in the device group and 67.2% in the control group (HR, 0.72; 95% CI, 0.58 to 0.89). Death or hospitalization for heart failure within 5 years occurred in 73.6% of the device group and in 91.5% of those in the control group (HR, 0.53; 95% CI, 0.44 to 0.64). During the 5-year study, device-specific safety events occurred in 1.4% of study participants (n=4 out of 293); all 4 events occurred within 30 days of the procedure (Stone, 2023).

In 2019, Arnold and colleagues reported findings from a prospective sub-study of the COAPT trial to better understand the health status outcomes of individuals with HF and 3-4+ secondary MR treated with TMVr versus standard care. At baseline, individuals had substantially impaired health status (mean Kansas City Cardiomyopathy Questionnaire (KCCQ) and SF-36 health status survey

[KCCQ-0S] 52.4 ± 23.0). The health status was unchanged over time in the standard care group, participants in the TMVr group demonstrated substantial improvement in the KCCQ-OS at "1 month (mean between-group difference 15.9 points, 95% CI 12.9 to 19.5 with only slight attenuation of this benefit through 24 months (mean between-group difference 12.8 points, 95% CI 7.5 to 18.2)". In conclusion, the authors reported that individuals with symptomatic HF and 3-4+ secondary MR who underwent TMVr with the edge-to-edge device resulted in substantial health status improvement compared with standard care. "This benefit emerged early, was consistent across key subgroups, and was sustained through 24 months follow-up."

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*)

The committee recommendations for TMVr with the MitraClip are based on results from the EVEREST II, MITRA-FR trial and COAPT trials.

In April 2022, AHA/ACC/Heart Failure Society of America (HFSA) guideline for the management of heart failure: a report of the ACC/American Heart Association Joint Committee on clinical practice guidelines (Heidenreich, 2022), authors included 2a recommendation for management of heart failure and secondary MR for transcatheter mitral edge -to-edge. The procedure:

> Has been shown to be beneficial in patients with persistent symptoms despite GDMT, appropriate anatomy on transesophageal echocardiography and with LVEF between 20% and 50%, LVESD ≤ 70 mm, and pulmonary artery systolic pressure ≤ 70 mm Hg.
>
> A cardiologist with expertise in the management of HF is integral to shared decision-making for valve intervention and should guide optimization of GDMT to ensure that medical options for HF and secondary MR have been effectively applied for an appropriate time period and exhausted before considering intervention.

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 June 2024.

Other Transcatheter Mitral Valve Procedures

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 September 2020, 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 replacement 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 replacement procedures is not known and requires further study. (Product Label Information, 2020)

Transcatheter Tricuspid Valve Repair or Replacement:

Tricuspid valve repair or replacement via a transcatheter approach, and devices for transcatheter tricuspid valve repair (TTVR) and replacement are in early stages of development for the treatment of tricuspid regurgitation. Early studies evaluated the 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).

In 2023, Sorajja and colleagues conducted a multi-center, prospective RCT of percutaneous TEER for individuals with severe, symptomatic tricuspid valve regurgitation. The primary end point was a composite score of death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and an improvement in quality of life as measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ), improvement defined as an increase of at least 15 points in the KCCQ score (range, 0 to 100, with higher scores indicating better quality of life) at the 1-year follow-up. The severity of tricuspid regurgitation and safety were also assessed. A total of 350 participants were enrolled (175 were randomly assigned to the device and control group, ultimately 170 were successfully implanted with the device). The primary end point marginally favored the TEER group (win ratio, 1.48; 95% CI, 1.06 to 2.13; p=0.02). No difference was detected between groups in the incidence of death or tricuspid-valve surgery nor the rate of hospitalization for heart failure. The KCCQ quality-of-life score changed by a mean (± SD) of 12.3 ± 1.8 points in the TEER group, as compared with 0.6 ± 1.8 points in the control group (p<0.001). At 30 days, 87.0% of the TEER group and 4.8% of those in the control group had tricuspid regurgitation of no greater than moderate severity (p<0.001). While TEER demonstrated an improvement in quality of life (self-reported measure), the difference did not reach the pre-specified 15-point improvement. Furthermore, there was only marginally significantl clinically meaningful benefits demonstrated in the study's primary composite outcome measure. Further study is warranted, including extended study duration beyond 30 days post procedure.

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 that 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. The TF vascular access approach has been associated with reduced vascular complications (Carrol, 2020). The 2020 ACC/AHA guideline (Otto, 2020) recommendations for TAVR in moderate or lower STS risk patients specify that the TF vascular access approach should be used. Registry data shows that more than 90% of TAVR in the U.S. is now performed with the TF approach.

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:

Manufacturer, TAVR (TAVI) Device and Indication	Date Approved	PMA
Abbott, Abbott Park, IL		
PORTICO™ with FLEXNAV™Transcatheter Aortic Valve Implantation System • Symptomatic, severe aortic stenosis at high or extreme risk for open surgical therapy • Navitor™ TAVI System; next generation of Portico™ TAVI System to treat people with severe aortic stenosis who are at high or extreme risk for open-heart surgery	September 2021 October 2022	P190023 P190023/S002
Edwards Lifesciences, Inc. Irvine, CA		
SAPIEN XT™ Transcatheter Heart Valve (model 9300TFX) and accessories • Severe native aortic valve stenosis at high or greater risk for open surgical therapy	July 2014	P13000
SAPIEN XT™ Transcatheter Heart Valve and accessories • Expanded to include failure (stenosed, insufficient, or combined) of surgical bioprosthetic valve in high or greater risk for open surgical therapy, 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	October 2015	P130009/034
SAPIEN XT Transcatheter Heart Valve • Expanded to include severe aortic stenosis with intermediate surgical risk	August 2016	P130009/S057
SAPIEN 3 Transcatheter Heart Valve • Severe aortic stenosis inoperable or at high risk for open surgical therapy • Expanded to include severe aortic stenosis with intermediate risk	June 2015 August 2016	P140031 P140031/S010
SAPIEN 3 Ultra Transcatheter Heart Valve • Severe aortic stenosis at intermediate or greater risk for open surgical therapy • Symptomatic heart disease due to failure (stenosed, insufficient, or combined) of surgical bioprosthetic 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)	June 2017	P140031/S028
SAPIEN 3 Transcatheter Heart Valve and SAPIEN 3 Ultra Transcatheter Heart Valve • Expanded to include severe aortic stenosis with low surgical risk	August 2019	P140031/S085
SAPIEN 3 Transcatheter Heart Valve and SAPIEN 3 Ultra Transcatheter Heart Valve • Expanded to include the replacement of failing (narrowed, leaking, or both) previously implanted transcatheter aortic or mitral valve	September 2020	P140031/S112
Medtronics, Inc., Santa Ana, CA		
Medtronic CoreValve System		

• Severe native aortic stenosis at extreme risk or inoperable for open surgical therapy	January 2014	P130021
• Expanded to include high-risk for open surgical therapy	June 2016	P130021/S002
• Expanded to include intermediate risk for open surgical therapy	July 2017	P130021/S033
• Medtronic CoreValve Evolut R System™ (design iteration for valve and accessories)	June 2015	P130021/S014
• Expanded to include intermediate risk for open surgical therapy • Expanded to include intermediate risk for open surgical therapy	July 2017	P130021/S033
• Expanded to include intermediate risk for open surgical therapy	March 2017	P130021/S029
• Expanded to include severe aortic stenosis with low surgical risk	August 2019	P130021/S058
• Medtronic CoreValve Evolut PRO+ System™ (design iteration)	August 2019	P130021/S059
Boston Scientific, Marlborough, MA		
LOTUS Edge Aortic Valve System • Severe native aortic stenosis at high or greater risk for open surgical therapy* *__Note:__ In November 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.	April 2019	P1800029
SENTINEL™ Cerebral Protection System • An embolic protection device to capture and remove thrombus/debris while performing TAVR procedures	January 2020	K192460

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

MitraClip NT Clip Delivery System and MitraClip NTR/XTR (Abbott Vascular, Menlo Park, CA)

- The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic MR ≥ 3+ due to primary abnormality of the mitral apparatus (degenerative MR) in individuals 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 benefit from reduction of the MR.

  The MitraClip NTR/XTR System, when used with maximally tolerated GDMT, is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) MR (MR ≥ Grade III per American Society of Echocardiography criteria) in individuals with left ventricular ejection fraction ≥ 20% and ≤ 50%. And a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of HF and mitral valve disease.

******The FDA has approved the following TPV for marketing:***

Medtronic Melody® TPV (Medtronic, Inc., Minneapolis, MN)

- The Melody Transcatheter Pulmonary Valve (TPV) has an HDE approval from the FDA (2015) 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. In 2017, this approval was expanded to include surgical bioprosthetic pulmonary valves (valve-in-valve) that have ≥ moderate regurgitation and/or a mean RVOT gradient ≥ 35 mmHg.

Medtronic Harmony™ TPV System (Medtronic, Inc., Minneapolis, MN)

- In the beginning of 2021, Medtronic, Inc. received FDA premarket approval the Harmony TPV System for use in the management of pediatric and adult candidates with severe pulmonary regurgitation (that is, severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitation fraction greater than or equal to 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical valve replacement.

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

- In 2016, the SAPIEN XT THV and delivery system (previously approved for TAVR) 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.

- In 2020, the Edwards SAPIEN 3 Valve System was approved for pulmonary valve replacement when a pulmonary valve conduit or artificial pulmonary valve stopped working properly.
- In 2021, the Edwards SAPIEN 3 Valve System approval was expanded for use in combination with the Alterra Adaptive Prestent in children and adults with severe pulmonary regurgitation who have a native or surgically-repaired (patched) RVOT.

Definitions

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

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
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) [add-on]
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) [add-on]
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) [add-on]
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
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
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach

ICD-10 Diagnosis

	All diagnoses

When services are Not Medically Necessary:
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	
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous [add-on]
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 (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
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
02RJ4JZ	Replacement of tricuspid valve with synthetic substitute, percutaneous endoscopic approach
ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Adams DH, Popma JJ, Reardon MJ, et al.; U.S. CoreValve Clinical Investigators. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med. 2014; 370(19):1790-1798.
2. Ailawadi G, Lim DS, Mack MJ, et al. One-year outcomes after MitraClip for functional mitral regurgitation. Circulation. 2019; 139:37-47.
3. Arnold SV, Chinnakondepalli KM, Spertus JA, et al. Health status after transcatheter mitral-valve repair in heart failure and secondary mitral regurgitation: COAP Trial. J Am Coll Cardiol. 2019; 73(17):2123-2132.
4. Arnold SV, Petrossian G, Reardon MJ, et al. Five-year clinical and quality of life outcomes from the CoreValve US Pivotal Extreme Risk Trial. Circ Cardiovasc Interv. 2021; 14(6):e010258.
5. Bleiziffer S, Ruge H, Mazzitelli D, et al. Valve implantation on the beating heart: catheter-assisted surgery for aortic stenosis. Dtsch Arztebl Int. 2009; 106(14):235-241.
6. Carrol JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT registry of transcatheter aortic valve replacement. J Amer Coll Cardiol. 2020; 76(21):2492-2516.
7. Case BC, Forrestal BJ, Yerasi C, et al. Real-world experience of the Sentinel Cerebral Protection Device: insights from the FDA Manufacturer and User Facility Device Experience (MAUDE) Database. Cardiovasc Revasc Med. 2020; 21(2):235-238.
8. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis. Circulation. 2002; 106(24):3006-3008.
9. Del Val D, Ferreira-Neto AN, Wintzer-Wehekind J, et al. Early experience with transcatheter mitral valve replacement: a systematic review. J Am Heart Assoc. 2019; 8(17):e013332.
10. Doshi R, Shah J, Patel V, et al. Transcatheter or surgical aortic valve replacement in patients with advanced kidney disease: A propensity score-matched analysis. Clin Cardiol. 2017; 40(11):1156-1162.
11. Dvir D, Webb JG, Bleiziffer S, et al.; Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves. JAMA. 2014; 312(2):162-170.
12. Feldman T, Foster E, Glower DD, et al.; EVEREST II Investigators. Percutaneous repair or surgery for mitral regurgitation. N Engl J Med. 2011; 364(15):1395-1406.
13. Feldman T, Kar S, Rinaldi M, et al.; EVEREST Investigators. Percutaneous mitral repair with MitraClip system: safety and midterm durability in the initial EVEREST (Endovascular Valve Edge-to-Edge Repair Study) cohort. J Am Coll Cardiol. 2009; 54(8):686-694.
14. Feldman T, Saibal K, Elmariah S, et al. Randomized comparison of percutaneous repair of surgery for mitral regurgitation. 5-year results of EVERST II. JACC. 2015; 66(25):2844-2854.
15. Feldman T, Wasserman HS, Herrmann HC, et al. Percutaneous mitral valve repair using the edge-to-edge technique: six-month results of the EVEREST Phase I Clinical Trial. J Am Coll Cardiol. 2005; 46(11):2134-2140.
16. Feldman TE, Reardon MJ, Rajagopal V, et al. Effect of mechanically expanded vs self-expanding transcatheter aortic valve replacement on mortality and major adverse clinical events in high-risk patients with aortic stenosis: The REPRISE III randomized clinical trial. JAMA. 2018; 319(1):27-37.
17. Giustino G, Camaj A, Kapadia SR, et al. Hospitalizations and mortality in patients with secondary mitral regurgitation and heart failure: The COAPT Trial. J Am Coll Cardiol. 2022; 80(20):1857-1868.
18. Gleason TG, Reardon MJ, Popma JJ. 5-Year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. J Am Coll Cardiol. 2018; 72(22):2687-2696.
19. Glower DD, Saibal K, Trento A, et al. Percutaneous mitral valve repair for mitral regurgitation in high-risk patients. Results of the EVEREST II study. JACC. 2014; 64(2):172-181.
20. Guerios EE, Gloekler S, Pilgrom T, et al. Second valve implantation for the treatment of a malpositioned transcatheter aortic valve. J Invasive Cardiol. 2012; 24(9):457-462.
21. Haas NA, Carere RG, Kretschmar O, et al. Early outcomes of percutaneous pulmonary valve implantation using the Edwards SAPIEN XT transcatheter heart valve system. Int J Cardiol. 2018; 250:86-91.
22. Halim SA, Edwards FH, Dai D, et al. Outcomes of transcatheter aortic valve replacement in patients with bicuspid aortic valve

disease: a report from The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. Circulation. 2020; 141(13):1071-1079.
23. Jones TK, McElhinney DB, Vincent JA, et al. Long-term outcomes after melody transcatheter pulmonary valve replacement in the US Investigational Device Exemption Trial. Circ Cardiovasc Interv. 2022; 15(1):e010852.
24. Kapadia SR, Leon MB, Makkar RR, et al.; PARTNER Trial Investigators. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomized controlled trial. Lancet. 2015; 385(9986):2485-2491.
25. Kapadia SR, Makkar R, Leon M, et al. Cerebral embolic protection during transcatheter aortic-valve replacement. N Engl J Med. 2022; 387(14):1253-1263.
26. Kar S, Feldman T, Qasim A, et al. Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients. Heart. 2019; 105(21):1622-1628.
27. Kodali SK, Williams MR, Smith CR, et al.; PARTNER Trial Investigators. Two-year outcomes after transcatheter or surgical aortic-valve replacement. N Engl J Med. 2012; 366(18):1686-1695.
28. Kolkailah AA, Doukky R, Pelletier MK, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis in people with low surgical risk. Cochrane Database Syst Rev. 2019;(12):CD013319.
29. Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 years after transcatheter aortic valve replacement in patients at low surgical risk. J Am Coll Cardiol. 2021; 77(9):1149-1161.
30. Leon MB, Smith CR, Mack M, et al.; PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010; 363(17):1597-1607.
31. Leon MB, Smith CR, Mack M, et al.; PARTNER 2 Investigators. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2016; 374(17):1609-1620.
32. Lim DS, Kim D, Aboulhosn J, et al. Congenital pulmonic valve dysfunction treated with SAPIEN 3 transcatheter heart valve (from the COMPASSION S3 Trial). Am J Cardiol. 2023; 190:102-109.
33. Machaalany J, Bilodeau L, Hoffmann R, et al. Treatment of functional mitral valve regurgitation with the permanent percutaneous transvenous mitral annuloplasty system: results of the multicenter international Percutaneous Transvenous Mitral Annuloplasty System to Reduce Mitral Valve Regurgitation in Patients with Heart Failure trial. Am Heart J. 2013; 165(5):761-769.
34. Mack MJ, Leon MB, Smith CR, et al.; PARTNER 1 Trial Investigatores. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high risk patients with aortic stenosis (PARTNER 1): a randomized controlled trial. Lancet. 2015; 385(9986):2477-2484.
35. Mack MJ, Leon MB, Thourani R, et al. Transcatheter aortic-valve replacement with balloon-expandable valve in low-risk patients. N Engl J Med. 2019; 380(18):1695-1705.
36. Maisano F, Franzen O, Baldus S, et al. Percutaneous mitral valve interventions in the real world: early and 1-year results from the ACCESS-EU, a prospective, multicenter, nonrandomized post-approval study of the MitraClip therapy in Europe. J Am Coll Cardiol. 2013; 62(12):1052-1061.
37. Makkar RR, Thourani VH, Mack MJ, et al. Five-year outcomes of transcatheter or surgical aortic-valve replacement. N Engl J Med. 2020; 382(9):799-809.
38. Makkar RR, Yoon SH, Leon MB, et al. Association between transcatheter aortic valve replacement for bicuspid vs tricuspid aortic stenosis and mortality or stroke. JAMA. 2019; 321(22):2193-2202.
39. Makkar RR, Yoon SH, Chakravarty T, et al. Association between transcatheter aortic valve replacement for bicuspid vs tricuspid aortic stenosis and mortality or stroke among patients at low surgical risk. JAMA. 2021; 326(11):1034-1044.
40. Mauri L, Foster E, Glower DD, et al.; EVEREST II Investigators. 4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation. J Am Coll Cardiol. 2013; 62(4):317-328.
41. Mauri L, Garq P, Massaro JM, et al. The EVEREST II Trial: design and rationale for a randomized study of the evalve mitraclip system compared with mitral valve surgery for mitral regurgitation. Am Heart J. 2010; 160(1):23-29.
42. McElhinney DB, Cheatham JP, Jones TK, et al. Stent fracture, valve dysfunction, and right ventricular outflow tract reintervention after transcatheter pulmonary valve implantation: patient-related and procedural risk factors in the US Melody Valve Trial. Circ Cardiovasc Interv. 2011; 4(6):602-614.
43. McElhinney DB, Hellenbrand WE, Zahn EM, et al. Short- and medium-term outcomes after transcatheter pulmonary valve placement in the expanded multicenter US melody valve trial. Circulation. 2010; 122(5):507-516.
44. Meadows JJ, Moore PM, Berman DP, et al. Use and performance of the Melody Transcatheter Pulmonary Valve in native and postsurgical, nonconduit right ventricular outflow tracts. Circ Cardiovasc Interv. 2014; 7(3):374-380.
45. Millan X, Skaf S, Joseph L, et al. Transcatheter reduction of paravalvular leaks: a systematic review and meta-analysis. Can J Cardiol. 2015; 31(3):260-269.
46. Obadia JF, Messika-Zeitoun D, Leurent G, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. N Eng J Med. 2018; 379(24):2297-2306.
47. O'Hair D, Yakubov SJ, Grubb KJ, et al. Structural valve deterioration after self-expanding transcatheter or surgical aortic valve implantation in patients at intermediate or high risk. JAMA Cardiol. 2023; 8(2):111-119.
48. Piazza N, van Gameren M, Jüni P, et al. A comparison of patient characteristics and 30-day mortality outcomes after transcatheter aortic valve implantation and surgical aortic valve replacement for the treatment of aortic stenosis: a two-centre study. EuroIntervention. 2009; 5(5):580-588.
49. Popma JJ, Adams DH, Reardon MJ, et al.; CoreValve United States Clinical Investigators. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. J Am Coll Cardiol. 2014; 63(19):1972-1981.
50. Popma JJ, Deed GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019; 380(18):1706-1715.
51. Popma JJ, Reardon MJ, Khabbaz K, et al. Early clinical outcomes after transcatheter aortic valve replacement using a novel self-expanding bioprosthesis in patients with severe aortic stenosis who are suboptimal for surgery: results of the Evolut R U.S. study. JACC Cardiovasc Interv. 2017; 10(3):268-275.
52. Reardon MJ, Van Mieghem JJ, Popma NS, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017; 376(14):1321-1331.
53. Reynolds MR, Magnuson EA, Lei Y, et al.; Placement of Aortic Transcatheter Valves (PARTNER) Investigators. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. Circulation. 2011; 124(18):1964-1972.
54. Ribeiro JM, Teixeira R, Lopes J, et al. Transcatheter versus surgical pulmonary valve replacement: A systemic review and meta-Analysis. Ann Thorac Surg. 2020; 110(5):1751-1761.
55. Rodés-Cabau J, Webb JG, Cheung A, et al. Transcatheter aortic valve implantation for the treatment of severe symptomatic aortic stenosis in patients at very high or prohibitive surgical risk: acute and late outcomes of the multicenter Canadian experience. J Am Coll Cardiol. 2010; 55(11):1080-1090.
56. Rogers T, Torguson R, Bastian R, Corso P, Waksman R. Feasibility of transcatheter aortic valve replacement in low-risk patients with symptomatic severe aortic stenosis: Rationale and design of the Low Risk TAVR (LRT) study. Am Heart J. 2017;

189:103-109.
57. Shahanavaz S, Balzer D, Babaliaros V, et al. Alterra Adaptive Prestent and SAPIEN 3 THV for Congenital Pulmonic Valve Dysfunction: An Early Feasibility Study. JACC Cardiovasc Interv. 2020a; 13(21):2510-2524.
58. Shahanavaz S, Berger F, Jones TK, et al. Outcomes after transcatheter reintervention for dysfunction of a previously implanted transcatheter pulmonary valve. JACC Cardiovasc Interv. 2020b; 13(13):1529-1540.
59. Shimamura J, Kuno T, Malik A, et al. Safety and efficacy of cerebral embolic protection devices in patients undergoing transcatheter aortic valve replacement: a meta-analysis of in-hospital outcomes. Cardiovasc Interv Ther. 2022; 37(3):549-557.
60. Siontis GCM, Overtchouk P, Cahill TJ, et al. Transcatheter aortic valve implantation vs. surgical aortic valve replacement for treatment of symptomatic severe aortic stenosis: an updated meta-analysis. Eur Heart J. 2019; 40:3143-3153.
61. Smith CR, Leon MB, Mack MJ, et al.; PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011; 364(23):2187-2198.
62. Sorajja P, Whisenant B, Hamid N, et al. Transcatheter repair for patients with tricuspid regurgitation. N Engl J Med. 2023 Mar 4. [Epub ahead of print].
63. Stone GW, Abraham WT, Lindenfeld J, et al. Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation. N Engl J Med. 2023 Mar 5. [Epub ahead of print].
64. Stone GW, Lindenfield JA, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. N Eng J Med. 2018; 379(24):2307-2318.
65. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet. 2016; 387(10034):2218-2225.
66. Thomas M, Schymik G, Walther T, et al. Thirty-day results of the SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry: A European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation. 2010; 122(1):62-69.
67. Thourani VH, Forcillo J, Beohar N, et al. Impact of Preoperative Chronic Kidney Disease in 2,531 High-Risk and Inoperable Patients Undergoing Transcatheter Aortic Valve Replacement in the PARTNER Trial. Ann Thorac Surg. 2016; 102(4):1172-1180.
68. Vahanian A, Alfieri O, Al-Attar N, et al. Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European association of cardio-thoracic surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). EuroIntervention. 2008; 4(2):193-199.
69. Van Mieghem NM, Deeb GM, Søndergaard L, et al. Self-expanding transcatheter vs surgical aortic valve replacement in intermediate-risk patients: 5-year outcomes of the SURTAVI randomized clinical trial. JAMA Cardiol. 2022; 7(10):1000-1008.
70. Waksman R, Rogers T, Torguson R, et al. Transcatheter aortic valve replacement in low-risk patients with symptomatic severe aortic stenosis. J Am Coll Cardiol. 2018; 72(18):2095-2105.
71. Whitlow PL, Feldman T, Pedersen WR, et al.; EVEREST II Investigators. Acute and 12-month results with catheter-based mitral valve leaflet repair: the EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study. J Am Coll Cardiol. 2012; 59(2):130-139.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Baumgartner H, Backer J, Babu-Narayan SV, et al. 2020 ESC Guidelines for the management of adult congenital heart disease: The Task Force for the management of adult congenital heart disease of the European Society of Cardiology (ESC). Eur Heart J. 2020; Available at: https://academic.oup.com/eurheartj/advance-article/doi/10.1093/eurheartj/ehaa554/5898606. Accessed on April 15, 2023.
2. Baumgartner H, Bonhoeffer P, De Groot NM, et al. European Society of Cardiology (ESC). ESC Guidelines for the management of grown-up congenital heart disease (new version 2010). The task force on the management of grown-up congenital heart disease of the European Society of Cardiology (ESC). Available at: https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Grown-Up-Congenital-Heart-Disease-Management-of Accessed on April 15, 2023.
3. Bonow RO, Carabello BA, Kanu C, et al. 2008 Focused update incorporated into the ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease): developed in collaboration with the Society of Cardiovascular Anesthesiologists: endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. Available at: http://circ.ahajournals.org/content/118/15/e523.full.pdf. Accessed on April 15, 2023.
4. Centers for Disease Control and Prevention (CDC). Valvular Heart Disease. Updated December 9, 2019. Available at: https://www.cdc.gov/heartdisease/valvular_disease.htm. Accessed on April 15, 2023.
5. Centers for Medicare and Medicaid Services National Coverage Determination (NCD). Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33). Effective January 19, 2021. Available at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=363&ncdver=2&. Accessed on April 15, 2023
6. Edwards Lifesciences. The PARTNER 3 – Trial – the safety and effectiveness of the SAPEIN 3 transcatheter heart valve in low risk patients with aortic stenosis (P3). NLM Identifier: NCT02675114. Last updated November 22, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT02675114. Accessed on April 15, 2023.
7. Evalve, Abbott Vascular. Cardiovascular outcomes assessment of the MitraClip Percutaneous therapy for heart failure patients with functional mitral regurgitation (The COAPT Trial) (COAPT). NLM Identifier: NCT01626079. Last updated September 28, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT01626079?term=NCT01626079&rank=1. Accessed on April 15, 2023.
8. Holmes DR, Mack MJ, Kaul S, et al. 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement, Journal of the American College of Cardiology (2012). Available at: https://www.jacc.org/doi/10.1016/j.jacc.2012.01.001. Accessed on April 15, 2023.
9. Hospices Civils de Lyon. Multicentre study of percutaneous mitral valve repair MitraClip device in patients with severe secondary mitral regurgitation (MITRA-FR). NLM Identifier: NCT01920698. Last updated July 10, 2018. Available at: https://clinicaltrials.gov/ct2/show/NCT01920698?term=NCT01920698&rank=1https://clinicaltrials.gov/ct2/show/NCT01920698?term=NCT01920698&rank=1. Accessed on April 15, 2023.
10. Medtronic Cardiovascular. Medtronic Evolut transcatheter aortic valve replacement in low risk patients. NLM Identifier: NCT02701283. Last updated October 26, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT02701283. Accessed on April 15, 2023.
11. Medtronic Cardiovascular. Safety and efficacy study of the Medtronic CoreValve System in the treatment of severe, symptomatic aortic stenosis in intermediate risk subjects who need aortic valve replacement (SURTAVI). (SURTAVI). NLM Identifier: NCT01586910. Last updated on November 02, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT01586910. Accessed on April 15, 2023.
12. Medtronic Heart Values. The Medtronic Harmony transcatheter pulmonary valve clinical study. NLM Identifier: NCT02979587. Last updated on January 30, 2023. Available at: https://www.clinicaltrials.gov/ct2/show/NCT02979587?

term=NCT02979587&draw=2&rank=1. Accessed on Accessed on April 15, 2023.
13. Nishimura R, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 Guideline for the management of patients with valvular heart disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2017; 70(2):252-289.
14. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2020; available at: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000923?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub 0pubmed. Accessed on April 15, 2023.
15. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling. Abbott PORTICO with FLEXNAV Transcatheter Aortic Valve Implantation System. Premarket approval application No. P190023. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190023. Accessed on April 15, 2023.
16. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling. Abbott PORTICO Navitor™ Transcatheter Aortic Valve Implantation (TAVI) System. Premarket approval application No. P190023/S002. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190023S012. Accessed on April 16, 2023.
17. U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Summary of Safety and Effectiveness and labeling: Boston Scientific Corporation, Sentinel Cerebral Protection System. 501(k) No. K192460. Maple Grove, MN: January 21, 2023. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K192460.pdf. Accessed on April 16, 2023.
18. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling. Medtronic CoreValve Evolute Pro System. Premarket approval application No. P130021/S029. March 20, 2017. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021S029. Accessed on April 15, 2023.
19. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Medtronic CoreValve Evolut R System and Medtronic CoreValve Evolut Pro System. Premarket Approval application No. P13022/S058. Rockville, MD: August 16, 2019. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021S058. Accessed on April 15, 2023.
20. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Medtronic CoreValve System. Premarket approval application No. P130021/S033. Rockville, MD: July 10, 2017. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021S033. Accessed on April 15, 2023.
21. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Medtronic Harmony Transcatheter Pulmonary Valve (TPV) System. Premarket approval application. P200046. Rockville, MD: March 26, 2021. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P200046. Accessed on April 15, 2023.
22. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling. MitraClip Clip Delivery System. Premarket approval application No. P100009. Rockville, MD: October 24, 2013. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=320432. Accessed on April 15, 2023.
23. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Edwards SAPIEN 3 Transcatheter Heart Valve. Premarket approval No. P140031/S028. Rockville, MD. June 5, 2017. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S028. Accessed on April 15, 2023.
24. U.S. Food and Drug Administration (FDA). Centers for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Edwards SAPIEN 3 Ultra Transcatheter Heart Valve. Premarket approval No.P140031/S074. Rockville, MD. December 27, 2018. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140031S074. Accessed on April 15, 2023.
25. U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Summary of Safety and Effectiveness and labeling: Edwards SAPEIN XT Transcatheter Heart Valve (THV) with the NovaFlex+ Delivery System. Premarket approval application No. P130009/S037. Rockville, MD: February 29, 2016. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130009S037. Accessed on April 15, 2023.
26. U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Summary of Safety and Effectiveness and labeling: Edwards SAPEIN XT Transcatheter Heart Valve (THV) Model 9300TFX, 23, 26, and 29mm and accessories. Premarket approval application No. P130009/S057. Rockville, MD: August 18, 2016. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130009S057d.pdf. Accessed on April 15, 2023.
27. U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Summary of Safety and Effectiveness and labeling: Edwards SAPIEN 3 Transcatheter Pulmonary Valve System Premarket approval application No. P200015. Rockville, MD: August 31, 2020. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200015B.pdf. Accessed on April 16, 2023.
28. U.S. Food and Drug Administration (FDA). Center for Devices and Radiologic Health (CDRH). Summary of Safety and Effectiveness and labeling: Edwards SAPIEN 3 Transcatheter Pulmonary Valve System With Alterra Adaptive Prestent. Premarket approval application No. P200015/S011. Rockville, MD: September 21, 2021. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200015A.pdf. Accessed on April 15, 2023.
29. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Medtronic CoreValve System. Premarket approval application No. P130021/S002. June 12, 2014. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130021S002. Accessed on April 15, 2023.
30. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and Probable Benefit: Melody Transcatheter Pulmonary Valve (TPV), Ensemble transcatheter valve delivery system (DS). Premarket approval application No. P140017. Rockville, MD: January 27, 2015. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=320589. Accessed on April 15, 2023.
31. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and Probable Benefit: Melody Transcatheter Pulmonary Valve (TPV), Ensemble transcatheter valve delivery system (DS). Premarket approval application No. P140017/2005. Rockville, MD: February 24, 2017. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140017S005B.pdf. Accessed on April 17, 2023.
32. U.S. Food and Drug Administration (FDA). Medical Devices. MitraClip NT Clip Delivery System and MitraClip NTR/XTR Clip Delivery System – P100009/S038. Rockville, MD: February 22, 2021. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P100009S038. Accessed on April 15, 2023.
33. Vahanian, A, Baumgartner H, Praz F, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Available at https://scc.org.co/wp-content/uploads/2018/10/2021-ESCEACTS-Guidelines-for-the-management-of-valvular-

heart-disease-1.pdf. Accessed on March 16, 2023.

Websites for Additional Information

1. American Heart Association. Available at: https://www.heart.org/. Accessed on April 15, 2023.
2. Cardiac Dimensions. Carillon Mitral Contour System. Available at:http://cardiacdimensions.com/. Accessed on April 15, 2023.
3. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Humanitarian Use Devices. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/default.htm. Accessed on April 15, 2023.

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
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised text and formatting in the MN statement for TAVR. Revised MN statement for TPVs to remove RVOT conduit diameter criteria and added criteria for native and patched RVOT. Added a new INV and NMN statement addressing TAVR cerebral protection devices. Revised the INV and NMN statement regarding valve-in-valve repair to address replacement instead of repair. Updated Discussion, Rationale, Background, Coding, References, and Websites sections.
Revised	08/11/2022	MPTAC review. Clarified TAVR MN clinical indications. Added MN statement for transcatheter Mitral Edge-to-Edge Repair/transcatheter mitral valve repair using an FDA approved device when criteria met. Added NMN statement for transcatheter mitral edge-to-edge repair/TMVr when the criteria above are not met. Revised INV/NMN statement for TMVr to address transcatheter mitral edge-to-edge repair for all “other” indications. Updated Discussion, Rationale, Background, References, Websites and Index sections. Updated Coding section and added ICD-10 procedure 02UG3JZ.
	12/29/2021	Updated Coding section with 01/01/2022 CPT changes; added 33370 effective 01/01/2022.
	11/22/2021	Updated Background, References and Index sections, adding information for PORTICO Transcatheter Aortic Valve Implantation System and updated the “Manufacturer, TAVR (TAVI) device and indication table”.
Revised	08/12/2021	MPTAC review. Clarified TAVR MN clinical criteria defining acronym for AVA. Revised MN criteria for TAVR in low open surgical risk to include individuals 65 years of age or older. Updated Rationale, Background, References, Websites and Index sections.
Revised	02/11/2021	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	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.
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	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.
