MEDICAL POLICY

MEDICAL POLICY DETAILS	
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. AORTIC VALVE

A. Based upon our criteria and assessment of the peer-reviewed literature, transcatheter aortic valve implantation (TAVI) also known as transcatheter aortic valve replacement (TAVR) with an U.S. Food and Drug Administration (FDA) approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling, may be considered **medically necessary** for patients with native valve aortic stenosis and any surgical risk level when **ALL** of the following conditions are present:
   1. Severe aortic stenosis (refer to Policy Guidelines) with a calcified aortic annulus;
   2. New York Heart Association heart failure class II, III, or IV symptoms;
   3. Left ventricular ejection fraction greater than 20%;
   4. Patient does not have a unicuspid aortic valves.

B. Based upon our criteria and assessment of the peer-reviewed literature, transcatheter aortic valve implantation (TAVI) with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve (valve-in-valve) may be considered **medically necessary** when **ALL** of the following conditions are present:
   1. Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve;
   2. New York Heart Association heart failure class II, III, or IV symptoms;
   3. Left ventricular ejection fraction greater than 20%;
   4. Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); or patient is an operable candidate but is at high risk for open surgery.

C. Based upon our criteria and assessment of the peer-reviewed literature, transcatheter aortic valve implantation (TAVI) has not been medically proven to be effective and, therefore, is considered **investigational** for all other indications.

II. MITRAL VALVE

A. Based upon our criteria and assessment of the peer-reviewed literature, transcatheter mitral valve repair (TMVR) with an U.S. Food and Drug Administration (FDA) approved device, may be considered **medically necessary** for patients with symptomatic, primary mitral regurgitation (MR), who are considered at prohibitive risk for open surgery (refer to Policy Guidelines).
B. Based upon our criteria and assessment of the peer-reviewed literature, TMVR with a U.S. Food and Drug Administration (FDA) approved device, may be considered **medically necessary** for patients with heart failure and moderate-to-severe or severe symptomatic secondary mitral regurgitation, despite the use of maximally tolerated guideline-directed medical therapy (refer to Policy Guidelines).
C. Based upon our criteria and assessment of the peer-reviewed literature, TMVR is considered **investigational** for all other indications.

III. PULMONARY VALVE
A. Based upon our criteria and assessment of the peer-reviewed literature, transcatheter pulmonary valve implantation (TPVI) with an U.S. Food and Drug Administration (FDA) approved valve, may be considered **medically necessary** for patients with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation with **ANY** of the following indications:
1. Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
2. Individuals with native or patched RVOT with at least moderate pulmonic regurgitation;
3. Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg);
4. Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

B. Based upon our criteria and assessment of the peer-reviewed literature, TPVI is considered **investigational** for all other indications.

IV. TRICUSPID VALVE
A. Based upon our criteria and the lack of peer-reviewed literature, transcatheter tricuspid valve repair or replacement (TTVR) is considered **investigational** for all indications.

V. OTHER
A. Based upon our criteria and the lack of peer-reviewed literature, transcatheter placement and removal of a cerebral embolic protection device is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. The STS Short-Term Risk Calculator allows you to calculate a patient's risk of mortality and morbidities for the most commonly performed cardiac surgeries. Information regarding the risk calculator can be found at: https://www.sts.org/resources/risk-calculator.

II. "Prohibitive Risk" for open surgery may be determined based on the presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater.

III. The U.S. Food and Drug Administration (FDA) Risk Levels for Open Surgery are defined as follows:
A. *Extreme risk or inoperable for open surgery*:
1. Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.

B. *High risk for open surgery:*
1. Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
2. Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.

C. *Intermediate risk for open surgery:*
1. Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.

D. *Low risk for open surgery:*

1. Society of Thoracic Surgeons predicted operative risk score of less than 3% or 4%.

IV. The New York Heart Association (NYHA) Heart Failure Classification (NYHA, 1994) are defined as follows:

A. *NYHA Functional Class I*: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

B. *NYHA Functional Class II:* Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.

C. *NYHA Functional Class III:* Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.

D. *NYHA Functional Class IV:* Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

V. Optimal medical therapy include evaluation for cardiac risk factors (e.g., hypertension, diabetes mellitus, and hyperlipidemia), lifestyle factors (exercise, diet, smoking, and weight), risk for thromboembolic events, and drug therapy (e.g., vasodilators, diuretics, nitrates, nifedipine, and beta-adrenergic blocker therapy).

DESCRIPTION

Transcatheter Aortic Valve Implantation or Replacement

Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries. Congenital abnormalities of the aortic valve (most commonly a bicuspid or unicuspid valve) increase the risk of aortic stenosis; however, aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease which include advanced age, male gender, smoking, hypertension, and hyperlipidemia. For symptomatic patients with severe aortic valve stenosis, the open-heart approach for surgical aortic valve replacement (SAVR) is currently the gold standard treatment. Long-term results are convincing, and even in octogenarians, SAVR is feasible with acceptable results. However, in patients with many co-morbidities, the outcome is less favorable, and many of these patients may be inoperable or carry an unacceptably high peri-operative risk.

Transcatheter aortic valve implantation (TAVI), also known as transcatheter aortic valve replacement (TAVR), represents an alternative to SAVR in patients who are elderly, inoperable or at high-risk for conventional surgery. TAVI is performed percutaneously, most often via the transfemoral artery approach but can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed to open up the stenotic area followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic valve annulus. The procedure is performed on the beating heart without cardiopulmonary bypass. Once the prosthetic valve is deployed, angiography, computed tomography (CT) angiography or echocardiography is performed to ensure successful implantation of the device.

The currently available transcatheter aortic valves approved by the U.S. Food and Drug Administration (FDA) include the balloon-expandable Edwards Sapien 3 and Edwards Sapien XT (Edwards Lifesciences, Irvine, CA) and self- expandable Medtronic Evolt R and Evolut PRO systems (Medtronic, Inc., Santa Rosa, CA). They are indicated for percutaneous aortic valve implantation in individuals with severe aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be high risk or inoperable for open aortic valve replacement. In September 2021, the FDA approved the Abbott Portico with FlexNav transcatheter aortic valve replacement (TAVR) system to treat people with symptomatic, severe aortic stenosis who are at high or extreme risk for open-heart surgery.

Transcatheter Mitral Valve Repair

Mitral Regurgitation (MR) is the second most common valvular heart disease, occurring in 7% of people, 75 years and older, and accounting for 24% of all patients with valvular heart disease. MR with accompanying valvular incompetence leads to left ventricular (LV) volume overload with secondary ventricular remodeling, myocardial dysfunction, and left

heart failure. Clinical signs and symptoms of dyspnea and orthopnea may also be present in patients with valvular dysfunction. MR severity is classified as mild, moderate, or severe disease on the basis of echocardiographic and/or angiographic findings (1+, 2+, and 3 to 4+ angiographic grade, respectively).

Patients with MR generally fall into two categories, primary (also called degenerative) and secondary (also called functional) MR. Primary MR results from a structural abnormality in the valve, which causes it to leak. This leak may be a result of a floppy, or prolapsed leaflet, or a ruptured cord, which caused the leaflet to detach partially causing the leaflet to flail. Because the primary cause is a structural abnormality, most cases of primary MR are surgically corrected. Secondary MR results from LV dilatation due to ischemic or dilated cardiomyopathy. This causes the mitral value (MV) leaflets not to coapt or meet in the center. Because the valves are structurally normal in secondary MR, correcting the dilated LV using medical therapy is the primary treatment strategy used in the United States.

Standard open MV repair requires thoracotomy and cardiopulmonary bypass, which may not be tolerated in the elderly or in patients with underlying cardiac disease or other co-morbid conditions. TMVR is a less invasive alternative to open surgical therapy. The MitraClip system consists of a catheter, a steerable sleeve, and the clip, which is 4-mm wide, and made of a cobalt-chromium alloy and polypropylene fabric. The MitraClip is deployed percutaneously via a transfemoral approach, with a transseptal puncture used to access the left side of the heart and the mitral valve. Placement of MitraClip leads to coapting (joining) of the mitral leaflets, which creates a double-orifice valve.

In October 2013, the MitraClip Clip Delivery System (Abbott Vascular) was approved by the FDA through the premarket approval process for treatment of "significant symptomatic mitral regurgitation (MR 3+ or greater) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at a prohibitive risk for mitral valve surgery by a heart team. FDA product code: NKM.

In March 2019, the FDA approved a new indication for MitraClip, for "treatment of patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy. Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators."

Transcatheter Pulmonary Valve Implantation

Congenital heart disease, including tetralogy of Fallot, pulmonary atresia, and transposition of the great arteries, is generally treated by surgical repair at an early age. This involves reconstruction of the right ventricular outflow tract (RVOT) and pulmonary valve using a surgical homograft or a bovine-derived valved conduit. These repairs are prone to the development of pulmonary stenosis or regurgitation over long periods of follow-up. Because individuals with surgically corrected congenital heart disease repair are living into adulthood, RVOT dysfunction following initial repair has become more common. Calcification of the RVOT conduit can lead to pulmonary stenosis, while aneurysmal dilatation can result in pulmonary regurgitation. RVOT dysfunction can lead to decreased exercise tolerance, potentially fatal arrhythmias, and/or irreversible right ventricular dysfunction.

Transcatheter pulmonary valve implantation (TPVI) is a less invasive alternative to open surgical pulmonary valve replacement or reconstruction for right ventricular outflow tract (RVOT) obstruction. Percutaneous pulmonary valve replacement may be indicated for congenital pulmonary stenosis. Pulmonary stenosis or regurgitation in a patient with congenital heart disease (CHD) who has previously undergone RVOT surgery are additional indications. Patients with prior CHD repair are at risk of needing repeated reconstruction procedures.

The Melody Transcatheter Pulmonary Valve (TPV) and the Ensemble Transcatheter Valve Delivery System are used together for percutaneous replacement of a dysfunctional pulmonary valve. The Melody valve consists of a section of bovine jugular vein with an intact native venous valve. The transcatheter delivery system consists of a balloon-in-balloon catheter with a retractable sheath and distal cup into which the valve is placed. The procedure is performed on a beating heart without the use of cardiopulmonary bypass. In January 2010, the Melody TPV, and the Ensemble Transcatheter Valve Delivery System (Medtronic) were approved by FDA under the HDE program and more recently in February of 2017 the FDA approval of the Melody system was expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve).

The Edwards SAPIEN XT Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) is composed of a stainless-steel frame with bovine pericardial tissue leaflets and available in 23- and 26-mm sizes. It includes a delivery accessories system. On February 29, 2016, it was approved by FDA as a supplement "for use in pediatric and adult patients with a dysfunctional, noncompliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and either pulmonary regurgitation ≥ moderate and/or mean RVOT gradient ≥ 35 mmHg."

The Medtronic Harmony Transcatheter Pulmonary Valve (TPV) System is the first FDA-approved (March 2021) transcatheter valve system specifically designed for use in the management of pediatric and adult patients with severe pulmonary regurgitation who have a native or surgically repaired right ventricular outflow tract (RVOT) and are clinically indicated for surgical pulmonary valve replacement.

Transcatheter Tricuspid Valve Repair or Replacement

Clinically significant tricuspid regurgitation (TR) is quite common with at least moderate TR occurring in greater than one in 200 of the general population and 4% of those greater than or equal to 75 years of age. The underlying etiology of TR is most commonly pulmonary hypertension, either from left-sided heart failure, mitral or aortic valve disease, or primary pulmonary causes. Atrial fibrillation may be both a marker of disease progression as well as a cause of annular dilatation due to atrial remodeling. Neither medical therapy nor conventional surgery is efficacious for most patients with significant TR. Currently, tricuspid valve surgery for functional TR is recommended only when performing surgery for concomitant left-sided valve disease. Devices for transcatheter tricuspid valve repair (TTVR) or replacement are in early stages of development for the treatment of tricuspid regurgitation and there are clinical studies evaluating the use of TTVR devices. Individual selection criteria for percutaneous tricuspid valve replacement are based on limited data.

Currently, there are no FDA-approved devices for transcatheter tricuspid valve repair (TTVR) or replacement.

The 2017 position statement of the European Society of Cardiology Working Groups of Cardiovascular Surgery and Valvular Heart Disease: Management of Tricuspid Valve Regurgitation states that "Percutaneous tricuspid valve intervention (both repair and replacement) is still in its infancy but may become a reliable option in future, especially for high-risk patients with isolated primary TR or with secondary TR related to advanced left sided heart valve disease."

Cerebral Embolic Protection Device

In June 2017, the Sentinel Cerebral Protection System (Boston Scientific; previously Claret Medical, Inc.) was granted a de novo classification by the FDA (DEN160043; class II; product code: PUM) (FDA, 2016). The Sentinel system is a temporary catheter indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 mm to 15 mm for the brachiocephalic and 6.5 mm to 10 mm in the left common carotid. The new classification applies to this device and substantially equivalent devices of this generic type.

On August 3, 2021, the FDA Circulatory System Devices Panel of the Medical Devices Advisory Committee met to discuss and make recommendations on the 510(k) submission for the TriGUARD 3 Cerebral Embolic Protection Device (Keystone Heart) (FDA, 2021). With the Sentinel system serving as the predicate device, the panel expressed that the proposed indications for use of the TriGUARD 3 device were not supported by the safety and effectiveness data from the REFLECT II trial **(**Aladin AI, et al., 2022).

RATIONALE

Transcatheter heart valve replacement is a less invasive alternative to conventional open-heart surgery as it does not require heart-lung bypass. A catheter inserted using a transfemoral (TF), transapical 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. 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 percent 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.

Transcatheter Aortic Valve Implantation or Replacement

TAVR is well established for the treatment of high-risk and inoperable patients with symptomatic severe aortic stenosis. A robust evidence base has compared transcatheter aortic valve replacement (TAVR) to the standard of care for aortic stenosis. The series of Placement of AoRTic TraNscathetER Valves (PARTNER) trials began with PARTNER 1B (n=358), which demonstrated superiority of TAVR to medical therapy in inoperable patients, with an absolute survival advantage of 23percent at five years (Leon et al., 2010). The PARTNER 1A (n=699) and CoreValve (n=795) trials randomized high–surgical risk patients between TAVR and surgical aortic valve replacement (SAVR) (Smith et al., 2011; Adams et al., 2014). Both trials were noninferiority trials and showed either no difference or improved survival with TAVR at one year. Patients in PARTNER 1A have been followed to five years with no survival difference seen (Sanchez et al., 2020; Reardon et al., 2019; Herrmann et al., 2019; Pibarot et al., 2019; Mack et al., 2015 and Kapadia et al., 2015).

Two multicenter randomized controlled studies have compared TAVR to surgical aortic valve replacement (SAVR) in symptomatic patients at intermediate surgical risk. The PARTNER 2A trial (Leon et al., 2016) randomized 2,032 patients to the balloon-expandable Sapien valve versus SAVR, and the SURTAVI trial (Reardon et al., 2017) randomized 1,660 patients to a self-expanding TAVR (CoreValve or Evolut-R) versus SAVR. The results of both trials demonstrated noninferiority of TAVR to SAVR for the composite endpoint of death and stroke at two years. In a large registry of symptomatic, intermediate-risk patients who underwent TAVR using the balloon-expandable Sapien 3 system (Thourani et al., 2016), survival was markedly superior to the surgical arm of the PARTNER 2A study (Herrmann et al., 2019).

Favorable short-term results with TAVR in low-risk patients were reported in two recent randomized clinical trials. The Evolut Low Risk Trial (Popma et al., 2019) reported the estimated two-year incidence of the primary endpoint, a composite of death or disabling stroke, was 5.3 percent in the TAVI group and 6.7 percent in the SAVR group showing non-inferiority of TAVI and SAVR, but no superiority for either mortality or stroke at one year. The PARTNER 3 Trial (Mack et al., 2019) low-risk patient study showed superiority of TAVI for stroke and the composite primary endpoint of death, stroke and rehospitalization at one year. The Nordic Aortic Valve Intervention Trial (NOTION) (Thyregod et al., 2019) randomized patients to receive TAVR or SAVR, and 82 percent of the patients were at low risk for surgical operations (i.e., Society of Thoracic Surgeons Predicted Risk of Mortality [STS-PROM] score less than 4 percent).

Similar outcomes were achieved in both TAVR and SAVR treatment arms at five years. Waksman et al. (2018) reported in a prospective study that transfemoral TAVR, using mainly a third-generation balloon-expandable TAVR device, was associated with no deaths at 30 days compared with 1.7 percent in a historical, propensity-matched SAVR cohort. The risk/benefit profile for periprocedural complications in low-risk patients is similar to the overall TAVR population (i.e., reduction in acute kidney injury and bleeding on the one hand and an increase in pacemaker implantation and vascular complications) (Overtchouk et al., 2019). The 2017 focused update to the 2014 American College of Cardiology (ACC) and American Heart Association (AHA) Practice Guideline for the Management of Patients with Valvular Heart Disease recommends surgical aortic valve replacement for low surgical risk patients (Nishimura et al., 2017). However, long-term follow-up data on outcomes and valve durability is needed.

In June 2019, the National Institute for Health and Care Excellence published interventional procedure guidance regarding valve-in-valve TAVI for aortic bioprosthetic valve dysfunction. The guidance recommendation is that "Current evidence on the safety and efficacy of valve-in-valve transcatheter aortic valve implantation for aortic bioprosthetic dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit."

In 2020, a new full ACC/AHA guideline was published that replaces the 2014 revision and 2017 focused update. The 2020 guidelines made recommendations on timing of intervention and choice of surgical or transcatheter intervention for treatment of aortic stenosis. Additionally, the guidelines state the following:

"Treatment of severe aortic stenosis with either a transcatheter or surgical valve prosthesis should be based primarily on symptoms or reduced ventricular systolic function. Earlier intervention may be considered if indicated by results of exercise testing, biomarkers, rapid progression, or the presence of very severe stenosis."

"Indications for TAVI are expanding as a result of multiple randomized trials of TAVI versus surgical aortic valve replacement. The choice of type of intervention for a patient with severe aortic stenosis should be a shared decision-making process that considers the lifetime risks and benefits associated with type of valve (mechanical versus bioprosthetic) and type of approach (transcatheter versus surgical)."

Transcatheter Mitral Valve Repair

Feldman et al. (2015) reported on the results of EVEREST II, an RCT that evaluated symptomatic or asymptomatic patients with grade 3+ or 4+ chronic MR who had SMR or primary MR etiology to TMVR at five years; patients were randomized to MitraClip or open MV repair/replacement, Most patients (73%) had primary MR and were eligible for mitral repair or replacement surgery. Results showed that TMVR was less effective at reducing MR and of subsequent surgery for MV dysfunction than conventional surgery, few patients experienced worsening MR or surgery after 6-month follow-up. There was no difference in long-term survival after TMVR compared to surgery and no decrement in left ventricle (LV) systolic function. Long-term survival was similar between the two treatment arms; however, functional MR and advanced age were associated with decreased survival regardless of the treatment.

The evidence for the use of MitraClip in patients with secondary mitral regurgitation (SMR) consists of two randomized-controlled-trials (RCTs), the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT), and the Percutaneous Repair with the MitraClip Device for Severe Functional/Secondary Mitral Regurgitation (MITRA-FR). Both trials compared MitraClip plus medical therapy to medical therapy alone in patients with SMR and heart failure, but they differed in their eligibility criteria, and primary outcome measures. COAPT enrolled 614 patients at 78 centers in the U.S. and Canada. MITRA-FR enrolled 304 patients at 37 centers in France. COAPT found a significant benefit for Mitraclip on the primary efficacy outcome (all HF hospitalizations within 24 months) and the primary safety outcome (freedom from device-related complications at 12 months). In contrast, the MITRA-FR investigators found no significant differences between Mitra-Clip plus medical therapy and medical therapy alone on the composite primary outcome (death from any cause or unplanned HF hospitalization at 12 months) or any secondary outcome, including all-cause mortality at 12 and 24 months and cardiovascular death at 12 and 24 months. Although the reasons for these discrepant results are not entirely clear, differences in the studies' design and conduct have been proposed as possible explanations. The severity of MR and heart failure among the patients in the trials differed. COAPT participants had more severe MR at baseline (effective regurgitant orifice area 41 versus 31 mm^2) and remained symptomatic despite the use of maximal doses of guideline-directed medical therapy. In both trials, eligible patients had to be symptomatic despite the use of optimal medical therapy. In COAPT, however, a central eligibility committee confirmed that the patient was using maximal doses of guideline-directed medical therapy prior to enrollment, and patients who improved with medical therapy were excluded. MITRA-FR had less stringent eligibility criteria and patients had more changes in medical therapy during the trial, indicating their treatment might not have been optimized. Additionally, patients in MITRA-FR had further progressed heart failure as indicated by LV dilation and may have been less likely to benefit from MR treatment. There is some evidence that technical success and procedural safety differed between the trials. Procedural complications were higher in MITRA-FR than in COAPT, and more patients in MITRA-FR experienced residual MR class greater than 3+ post-procedure (both acutely and at 12 months).

A Report of the American College of Cardiology (ACC)/American Heart Association (AHA) Joint Committee on Clinical Practice Guidelines for the Management of Patients with Valvular Heart Disease (2020) recommendations for intervention for chronic primary MR regarding transcatheter edge-to-edge repair (TEER) include the following: (1) 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 valve anatomy is favorable for the repair procedure and patient life expectancy is at least one year: Class: 2a; Level of Evidence: B-R; (2) In symptomatic patients with severe primary MR attributable to rheumatic valve disease, mitral valve repair may be considered at a Comprehensive Valve Center by an experienced team when surgical treatment is indicated, if a durable and successful repair is likely: Class: 2b; Level of Evidence: B-R; (3) In patients with chronic severe secondary MR related to LV systolic dysfunction (LVEF less than 50%) who have persistent severe symptoms (NYHA class II, III, or IV) while on optimal guideline directed medical therapy (GDMT) for HF (Stage D), TEER is reasonable in patients with appropriate anatomy as defined on transesophageal echocardiography (TEE) and with LVEF between 20% and 50%, LVESD 70 mm or less, and pulmonary

artery systolic pressure 70 mm Hg or less (Class: 2a; Level of Evidence: B-R). In summary, a mitral transcatheter edge-to-edge repair is of benefit to patients with severely symptomatic primary mitral regurgitation who are at high or prohibitive risk for surgery, as well as to a select subset of patients with secondary mitral regurgitation who remain severely symptomatic despite GDMT for heart failure. ACC/AHA guidelines for the management of patients with valvular heart disease (Nishimura et al., 2017) make the following recommendations regarding transcatheter valve replacement: Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal guideline-directed medical therapy for heart failure. (Class IIb recommendation, level of evidence B - Procedure may be considered but usefulness/efficacy is less well established based on conflicting evidence from a single randomized trial or nonrandomized studies.)

Transcatheter Pulmonary Valve Implantation

Transcatheter pulmonary valve (TPV) placement was first reported in 2000. Beginning in January 2007, the Melody TPV (Medtronic, Inc., Santa Ana, CA) was implanted in 150 patients at five US centers under an Investigational Device Exemption (IDE) protocol for treatment of right ventricular outflow tract (RVOT) dysfunction. In January 2010, enrollment in the US Melody Valve IDE trial was completed, and the Melody valve was approved for placement in dysfunctional RVOT conduits as a palliative measure aimed at delaying surgical intervention (McElhinney et al., 2011). The trial was initially designed to follow patients for five years after implantation or until explanation but was modified in 2011 to allow follow-up out to 10 years in patients who provided supplemental written informed consent (Cheatham et al., 2015).

In January 2015, the Melody TPV received Pre-Market Approval (PMA) from the FDA approval based on clinical evidence from three clinical studies that followed patients implanted with Melody TPV (i.e., the Melody U.S. IDE Study, the Melody U.S. Post Approval Study [PAS] and the European and Canadian Post- Market Surveillance Study [PMSS]). On February 24, 2017, approval of the Melody system was expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve). Per the FDA Summary of Effectiveness and Safety Data (SSED), the clinical data supporting the PMA supplemental approval decision were pooled from the following three (3) sources: Melody Transcatheter Pulmonary Valve (TPV) Long-term Follow-up Post Approval Study (PAS) n=8 patients; Melody TPV New Enrollment PAS n=17 patients and Real-World Data n=100 patients.

Cheatham et al. (2015) evaluated the midterm hemodynamic and clinical outcomes in the U.S. Melody Valve IDE trial patients (n=148), who were all at least four years out from Melody valve implantation. The nonrandomized IDE trial prospectively enrolled pediatric and adult patients (median age, 19 years) with right ventricular outflow tract conduit obstruction or regurgitation. The patients received and were discharged with a TPV were followed up annually according to a standardized protocol. During a median follow-up of 4.5 years (range, 0.4-7 years), 32 patients underwent right ventricular outflow tract reintervention for obstruction (n=27, with stent fracture in 22), endocarditis (n=3, 2 with stenosis and 1 with pulmonary regurgitation), or right ventricular dysfunction (n=2). Eleven patients had the TPV explanted as an initial or second reintervention. Five-year freedom from reintervention and explanation was 76±4 percent and 92±3 percent, respectively. A conduit present and lower discharge right ventricular outflow tract gradient were associated with longer freedom from reintervention. In the 113 patients who were alive and reintervention free, the follow-up gradient (median, 4.5 years after implantation) was unchanged from early post-TPV replacement, and all but one patient had mild or less pulmonary regurgitation. Almost all patients were in New York Heart Association class I or II. More severely impaired baseline spirometry was associated with a lower likelihood of improvement in exercise function after TPV replacement. The authors reported that TPV replacement with the Melody valve provided good hemodynamic and clinical outcomes up to seven years after implantation. Primary valve failure was rare. The main cause of TPV dysfunction was stenosis related to stent fracture, which was uncommon once presenting became more widely adopted.

In February 2016, the SAPIEN XT Transcatheter Heart Valve received Pre-Market Approval (PMA) from the FDA approval based on clinical evidence from the Congenital Multicenter trial of Pulmonic Valve regurgitation Studying the SAPIEN InterventIONal (COMPASSION) THV trial. The 2016 FDA PMA approval states that Edwards agreed to conduct a study to evaluate long-term safety and effectiveness of the SAPIEN XT THV in the pulmonic position for the intended patient population (especially pediatric) when used as indicated with all valve sizes. It is a single-arm,

prospective, multicenter post approval study using a performance goal based on the original COMPASSION trial. The study patients are pediatric and adult patients with a dysfunctional, non-compliant right ventricular outflow tract (RVOT) conduit with a clinical indication for intervention and pulmonary regurgitation greater than or equal to moderate and/or mean RVOT gradient greater than or equal to 35 mmHg. The eligibility criteria were consistent with the final FDA-approved IFU and labeling. A sample size of 162 subjects was required for the hypothesis test on the primary effectiveness endpoint with at least 80 percent of the power. A total of 191 patients were enrolled at up to 10 sites in the United States to account for loss to follow-up. The patients are being followed at hospital discharge: 30 days, one year and annually thereafter through five years.

The AHA/ACC Practice Guideline for the Management of Patients with Valvular Heart Disease does not make specific recommendations regarding the treatment of primary pulmonary valve disease (Nishimura et al, 2017).

The ACC/AHA 2018 Guidelines for the Management of Adults with Congenital Heart Disease (Stout et al., 2018) addresses percutaneous pulmonary replacement with recommendations for Tetralogy of Fallot (TOF) stating:

Pulmonary valve replacement (surgical or percutaneous) for relief of symptoms is recommended for patients with repaired TOF and moderate or greater pulmonary regurgitation (PR) with cardiovascular symptoms not otherwise explained (Class or Recommendation I; Level of evidence B-NR)

Pulmonary valve replacement (surgical or percutaneous) is reasonable for preservation of ventricular size and function in asymptomatic patients with repaired TOF and ventricular enlargement or dysfunction and moderate or greater PR (Class or Recommendation IIa; Level of evidence B-NR)

Transcatheter Tricuspid Valve Repair or Replacement

Tricuspid valve repair or replacement via transcatheter approach devices are in early stages of development for the treatment of tricuspid regurgitation. There are small case series as well as ongoing clinical trials for patients with diseased tricuspid valves undergoing transcatheter tricuspid valve replacement. There is currently insufficient published evidence to assess the safety and/or impact on health outcomes of transcatheter tricuspid valve replacement in patients with diseased tricuspid valves.

Nickenig et al. (2019) report the 6-month safety and performance of a transcatheter tricuspid valve reconstruction system in the treatment of moderate to severe functional tricuspid regurgitation (TR) in 30 patients enrolled in the TRIREPAIR (TrIcuspid Regurgitation RePAIr with CaRdioband Transcatheter System) study. Between October 2016 and July 2017, 30 patients were enrolled in this single-arm, multicenter, prospective trial. Patients were diagnosed with moderate to severe, symptomatic TR in the absence of untreated left-heart disease and deemed inoperable because of unacceptable risk for open-heart surgery by the local heart team. Clinical, functional, and echocardiographic data were prospectively collected before and up to six months post-procedure. An independent core lab assessed all echocardiographic data, and an independent clinical event committee adjudicated the safety events. Mean patient age was 75 years, 73 percent were female, and 23 percent had ischemic heart disease. At baseline, 83 percent were in New York Heart Association (NYHA) functional class III to IV and mean left ventricular ejection fraction was 58 percent. Technical success was 100 percent.

Three (3) patients died post procedure through six (6) months. Between six (6) months and baseline, echocardiography showed average reductions of annular septolateral diameter of 9 percent (42 mm vs. 38 mm; $p<0.01$) proximal isovelocity surface area effective regurgitant orifice area of 50 percent (0.8 cm2 vs. 0.4 cm2; $p <0.01$) and mean vena contracta width of 28 percent (1.2 cm vs. 0.9 cm; $p<0.01$). Clinical assessment showed that 76 percent of patients improved by at least 1 NYHA functional class with 88% in NYHA functional class I or II. Six (6) minute walk distance improved by 60 m ($p <0.01$), and Kansas City Cardiomyopathy Questionnaire score improved by 24 points ($p <0.01$). In conclusion, six (6) month outcomes show that the system performs as intended and appears to be safe in patients with symptomatic and moderate to severe functional TR. Significant reduction of TR through decrease of annular dimensions, improvements in heart failure symptoms, quality of life, and exercise capacity were observed. Further studies are warranted to validate these initial promising results.

Taramasso et al. (2019) reported on a large, prospective international registry which was developed to evaluate the initial clinical applications of transcatheter tricuspid valve intervention (TTVI) with different devices. TTVI for native tricuspid valve dysfunction has been emerging during the last few years as an alternative therapeutic option to serve a large high-

risk population of patients with severe symptomatic tricuspid regurgitation (TR). The TriValve Registry included 312 high-risk patients with severe TR (76.4 +/- 8.5 years of age; 57% female; EuroSCORE II 9 +/- 8%) at 18 centers.

Interventions included repair at the level of the leaflets (MitraClip, Abbott Vascular, Santa Clara, California; PASCAL Edwards Lifesciences, Irvine, California), annulus (Cardioband, Edwards Lifesciences; TriCinch, 4tech, Galway, Ireland; Trialign, Mitraling, Tewksbury, Massachusetts), or coaptation (FORMA, Edwards Lifesciences) and replacement (Caval Implants, NaviGate, NaviGate Cardiac Structures, Lake Forest, California). Clinical outcomes were prospectively determined during mid-term follow-up. A total of 108 patients (34.6%) had prior left heart valve intervention (84 surgical and 24 transcatheter, respectively). TR etiology was functional in 93 percent, and mean annular diameter was 46.9 +/- 9mm. In 75 percent of the patients, the regurgitant jet was central (vena contracta 1.1 +/- 0.5; effective regurgitant orifice area 0.78 +/- 0.6 cm(2)). Pre-procedural systolic pulmonary artery pressure was 41 +/- 14.8 mm Hg. Implanted devices included: MitraClip in 210 cases, Trialign in 18 cases, TriCinch first generation in 14 cases, caval valve implantation in 30 cases, FORMA in 24 cases, Cardioband in 13 cases, NaviGate in six cases, and PASCAL in one case. In 64 percent of the cases, TTVI was performed as a stand-alone procedure. Procedural success was defined as successful device implantation and residual TR. The report concluded that TTVI is feasible with different technologies, has a reasonable overall procedural success rate, and is associated with low mortality and significant clinical improvement. Mid-term survival of this high-risk population is favorable. The report also noted that greater coaptation depth is associated with reduced procedural success, which is an independent predictor of mortality.

Kodali et al. (2023) published one year outcomes from the TRISCEND study which evaluates the safety and performance of the EVOQUE tricuspid valve (TV) replacement system (Edwards Lifesciences, Irvine, CA) in patients with moderate and greater symptomatic TR despite medical therapy. This global, prospective, single-arm, multicenter TRISCEND study enrolled 176 patients who were 71.0% female, mean age 78.7 years, 88.0% ≥ severe TR, and 75.4% New York Heart Association classes III–IV. Major adverse events, reduction in TR grade and hemodynamic outcomes by echocardiography, and clinical, functional, and quality-of-life parameters are reported to one year. Tricuspid regurgitation was reduced to ≤mild in 97.6% ($P < .001$), with increases in stroke volume (10.5 ± 16.8 mL, $P < .001$) and cardiac output (0.6 ± 1.2 L/min, $P < .001$). New York Heart Association class I or II was achieved in 93.3% ($P < .001$), Kansas City Cardiomyopathy Questionnaire score increased by 25.7 points ($P < .001$), and six-minute walk distance increased by 56.2 m ($P < .001$). All-cause mortality was 9.1%, and 10.2% of patients were hospitalized for heart failure. The study showed in an elderly, highly comorbid population receiving transfemoral EVOQUE transcatheter TV replacement had sustained TR reduction, significant increases in stroke volume and cardiac output, and high survival and low hospitalization rates with improved clinical, functional, and quality-of-life outcomes to one year. This study has several limitations including being funded by Edwards Lifesciences with a single-arm design and no comparison to standard of care. This is an interim analysis and not all enrolled patients had yet reached their one-year follow-up. TTVR is an evolving field and standardized criteria for data collection and clinical trial definitions continue to develop.

Cerebral Embolic Protection Device

Kapadia et al. (2022) published results of the prospective, post market, multicenter, randomized, controlled PROTECTED TAVR trial. The aim was to evaluate the efficacy of intraprocedural cerebral embolic protection (CEP) in reducing strokes among patients undergoing transfemoral TAVR for aortic stenosis. A total of 3,000 patients at 51 centers across North America, Europe, and Australia were enrolled and underwent randomization from February 2020 through January 2022. Patients were randomized in 1:1 fashion to either CEP (n = 1,501) or control (n =1,499). A Sentinel device (Boston Scientific) was used for CEP. All investigators had performed at least 20 procedures involving its use. The primary outcome, stroke within 72 hours of TAVR or before discharge for CEP vs. control, was: 2.3% vs. 2.9% ($p = 0.30$). The results of this trial show that routine use of a CEP device does not result in a lower risk of stroke within 72 hours among patients undergoing transfemoral TAVR for aortic stenosis. This is the largest trial on this topic to date and further studies are warranted.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*

- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)*

CPT Codes

Code	Description
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus
0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
0545T **(E/I)**	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
0569T **(E/I)**	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis
0570T **(E/I)**	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)
0646T **(E/I)**	Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	open femoral artery approach
33363	open axillary artery approach
33364	open iliac artery approach
33365	transaortic approach (e.g., median sternotomy, mediastinotomy)
33366	transapical exposure (e.g., left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
33370 **(E/I)**	Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis
33419	additional prosthesis(es) during same session (List separately in addition to code for primary procedure)

33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

HCPCS Codes

Code	Description
No Codes	

ICD10 Codes

Code	Description
Multiple Diagnosis Codes	

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*Key Articles

KEY WORDS

Transcatheter aortic valve implantation (TAVI), Transcatheter aortic valve replacement (TAVR), Surgical aortic valve repair (SAVR), Transcatheter mitral valve repair (TMVR), MitraClip, Transcatheter pulmonic valve implantation (TPVI), Percutaneous pulmonary valve implantation (PPVI), Melody TPV System, Harmony TPV System, Transcatheter Tricuspid Valve Repair (TTVR), cerebral embolic protection device (CEPD)

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (#20.32). Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/ncd- details.aspx?NCDid=355] accessed 01/24/24.

The Centers for Medicare & Medicaid Services (CMS) covers TAVR under Coverage with Evidence Development (CED) with certain conditions. Please refer to the following CED website for Medicare Members: [https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR] accessed 01/24/24.

There is currently a National Coverage Determination (NCD) for Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (#20.33). Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=363&ncdver=3&DocID=20.33&bc=gAAAAAgAAAAA] accessed 01/24/24.

The Centers for Medicare & Medicaid Services (CMS) covers TMVR for MR under Coverage with Evidence Development (CED). Please refer to the following CED website for Medicare Members: [https://www.cms.gov/medicare/coverage/evidence/edge-to-edge-repair-teer] accessed 01/24/24.

The Centers for Medicare & Medicaid Services (CMS) covers Transcatheter Edge-to-Edge Repair (T-TEER) for Tricuspid Valve Regurgitation under Coverage with Evidence Development (CED). Please refer to the following NCD website for Medicare Members: [https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=381&ncdver=1&keywordtype=starts&keyword=t-teer&bc=0] accessed 08/25/25.

Based upon our review, Transcatheter Pulmonary Valve Implantation (TPVI) and Transcatheter Tricuspid Valve Replacement (TTVR) are not addressed in National or Local Medicare coverage determinations or policies.