MEDICAL POLICY

Medical Policy Title	**Transcatheter Heart Valve Procedures**
Policy Number	**7.01.109**
Current Effective Date	**January 1, 2027**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Aortic Valve

I. Transcatheter aortic valve implantation (TAVI) or transcatheter aortic valve replacement (TAVR) 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:
   A. Performed with a U.S. Food and Drug Administration (FDA) approved device;
   B. Performed via an approach consistent with the device's FDA-approved labeling;
   C. Severe aortic stenosis (refer to Policy Guidelines) with a calcified aortic valve;
   D. New York Heart Association heart failure class II, III, or IV symptoms;
   E. Left ventricular ejection fraction greater than 20%;
   F. Patient does not have a unicuspid aortic valve.

II. Transcatheter aortic valve-in-valve implantation may be considered **medically necessary** when **ALL** of the following conditions are present:
   A. Performed with a device FDA approved for repair of a degenerated bioprosthetic valve (valve-in-valve) use;
   B. Failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve;
   C. New York Heart Association heart failure class II, III, or IV symptoms;
   D. Left ventricular ejection fraction greater than 20%;
   E. Documentation of surgery risk by at least two (2) cardiovascular specialists (including a cardiac surgeon) shows **ANY** of the following:
      1. Patient is not a candidate for open surgery;
      2. Patient is an operable candidate but is at high risk for open surgery; or
      3. Patient is considered at increased surgical risk for open surgery (e.g., repeat sternotomy) due to a history of congenital vascular anomalies or has a complex intrathoracic surgical history.

III. Transcatheter aortic valve implantation (TAVI) is considered **investigational** for all other indications.

Mitral Valve

IV. Transcatheter mitral valve repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve may be considered **medically necessary** when **ALL** of the following criteria are met:
    A. Performed with a U.S. Food and Drug Administration (FDA) approved device;
    B. For **EITHER** of the following conditions:
        1. symptomatic, primary mitral regurgitation (MR),
            a. considered at prohibitive risk for open surgery (refer to Policy Guidelines); or
        2. heart failure and moderate-to-severe or severe symptomatic secondary mitral regurgitation,
            a. despite the use of maximally tolerated guideline-directed medical therapy (refer to Policy Guidelines).

V. Transcatheter mitral valve procedures are considered **investigational** for all other indications, including but not limited to:
    A. Transcatheter mitral valve implantation (TMVI), including mitral valve-in-valve replacement (TMViVR);
    B. Transcatheter mitral valve annuloplasty (annulus reconstruction).

Pulmonary Valve

VI. Transcatheter pulmonary valve implantation (TPVI) may be considered **medically necessary** when **ALL** of the following criteria are met:
    A. With a U.S. Food and Drug Administration (FDA) approved valve;
    B. Congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation with **ANY** of the following indications:
        1. Right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
        2. Native or patched RVOT with at least moderate pulmonic regurgitation;
        3. Right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
        4. Native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

VII. Transcatheter pulmonary valve implantation (TPVI) is considered **investigational** for all other indications.

Tricuspid Valve

VIII. Transcatheter tricuspid valve repair or replacement (TTVR/T-TEER) is considered **investigational** for all indications.

Other

IX. Transcatheter placement and removal of a cerebral embolic protection device is considered **investigational** for all indications.

X. Transcatheter superior and inferior vena cava prosthetic valve/Caval valve implantation (CAVI) is considered **investigational** for all indications.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The Society of Thoracic Surgeons (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/acsd-operative-risk-calculator [accessed 2026 Apr 30]

II. "Prohibitive Risk" for open surgery may be determined based on:

   A. Presence of a Society for Thoracic Surgeons predicted mortality risk of 12% or greater; or

   B. Presence of a logistic EuroSCORE of 20% or greater.

III. The FDA Risk Levels for Open Surgery are defined as follows:

   A. Extreme risk or inoperable for open surgery:

      - Predicted risk of operative mortality and/or serious irreversible morbidity 50% or higher for open surgery.

   B. High risk for open surgery:

      - Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
      - 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:

      - Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.

   D. Low risk for open surgery:

      - 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. Moderate to severe or severe mitral regurgitation (MR) may be determined by:

A. Grade 3+ (moderate) or 4+ (severe) MR confirmed by echocardiography;

B. New York Heart Association (NYHA) functional class II, III, or IVa (ambulatory) despite the use of stable maximal doses of guideline-directed medical therapy and cardiac resynchronization therapy (if appropriate) administered in accordance with guidelines of professional societies.

VI. Optimal medical therapy includes 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).

VII. Severe aortic stenosis is defined by the presence of **ANY** of the following criteria:

A. An aortic valve area of less than or equal to 1 cm2;

B. An aortic valve area index of less than or equal to 0.6 cm2/m2;

C. A mean aortic valve gradient greater than or equal to 40 mmHg; or

D. A peak aortic-jet velocity greater than or equal to 4.0 m/s.

DESCRIPTION

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.

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.

Transcatheter Mitral Valve Repair

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.

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.

Transcatheter Mitral Valve Implantation

Mitral valve-in-valve replacement is a minimally invasive procedure designed to treat patients with failing surgical bioprosthetic mitral valves who are at high risk for complications with repeat open-heart surgery. The procedure involves deploying the replacement valve within the failing bioprosthetic valve using a catheter-based transapical or transseptal approach. Once in position, the replacement valve is expanded, pushing the leaflets of the failing bioprosthetic valve aside and taking over the valve function.

Transcatheter Mitral Valve Annuloplasty

Transcatheter mitral valve annuloplasty (annulus reconstruction) (e.g., Carillon Mitral Contour System) attempts to enable effective leaflet function by reshaping the mitral annulus (ring around the valve) from within the coronary sinus, flexible rings or bands are implanted to improve the structure of the valve and purportedly reduce mitral regurgitation.

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 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.

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 and is approved 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 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.

Transcatheter Caval Valve Implantation

Transcatheter caval valve implantation (CAVI) is a technique proposed to relieve the symptoms of severe tricuspid regurgitation (e.g., ascites, dyspnea, fatigue, lower extremity edema) without repairing or replacing the tricuspid valve. This is accomplished by implanting a valve in the inferior vena cava (IVC) alone or in combination with a second valve in the superior vena cava (SVC) to redirect the regurgitant blood flow from the failing tricuspid valve.

Cerebral Embolic Protection Device

The Sentinel Cerebral Protection System (Boston Scientific; previously Claret Medical, Inc.) 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.

SUPPORTIVE LITERATURE

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 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 2011; Adams 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 2020; Reardon 2019; Herrmann 2019; Pibarot 2019; Mack 2015 and Kapadia 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 2016) randomized 2,032 patients to the balloon-expandable Sapien valve versus SAVR, and the SURTAVI trial (Reardon 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 2016), survival was markedly superior to the surgical arm of the PARTNER 2A study (Herrmann 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 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 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 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 four 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 2019).

Aedma et al (2022) conducted an umbrella meta-meta-analysis evaluating the efficacy and safety of valve-in-valve (ViV) TAVI compared to redo-surgical aortic valve replacement (rSAVR). Nine analyses,

which compared the two (2) modalities head-to-head in terms of outcomes and complications, were included for review. ViV TAVI was associated with a significantly lower risk of 30-day mortality (OR, 0.60; 95% CI, 0.53 to 0.68; p<.00001) and procedural mortality (OR, 0.52; 95% CI, 0.27 to 0.98; p=.04). No significant differences in long-term mortality (1 year follow-up) or hospital readmissions were identified. ViV TAVI was also associated with a lower risk several complications, including stroke (OR, 0.71; 95% CI, 0.59 to 0.84; p<.001), major bleeding (OR, 0.44; 95% CI, 0.35 to 0.57; p<.000001), acute kidney injury (OR, 0.57; 95% CI, 0.43 to 0.75; p<.0001), and pacemaker implantation (OR, 0.67; 95% CI, 0.52 to 0.86; p<.002). No association of acute myocardial infarction with ViV TAVI and redo-SAVR was found (OR, 1.15; 95% CI, 0.84 to 1.59; p=.38); however, ViV TAVI was associated with a higher risk of vascular complications (OR, 2.70; 95% CI, 1.58 to 4.62; p<.0003).

Raschpichler et al (2022) published a systematic review and meta-analysis of nonrandomized studies comparing ViV TAVI with redo-SAVR. A total of 15 studies including 8,881 patients were identified for analysis, which included 4,458 patients (50.2%) treated with ViV TAVI and 4,423 patients (49.8%) treated with redo-SAVR. Short-term mortality (<30 days) was 2.8% in patients undergoing ViV TAVI compared with 5.0% in patients undergoing redo-SAVR (RR, 0.55; 95% CI, 0.34 to 0.91). Midterm mortality (up to 5 years) was not significantly different between groups (HR, 1.27; 95% CI, 0.72 to 2.25). The rate of acute kidney failure was lower following ViV (RR, 0.54; 95% CI, 0.33 to 0.88); however, prosthetic aortic valve regurgitation (RR, 4.18; 95% CI, 1.88 to 9.3; p=.003) and severe patient-prosthesis mismatch (RR, 3.12; 95% CI, 2.35 to 4.1; p<.001) occurred more frequently. Additionally, the transvalvular gradient was significantly higher following ViV procedures (standard mean difference, 0.44; 95% CI, 0.15 to 0.72; p=.008). There were no significant differences between groups with respect to stroke (p=.26), myocardial infarction (p=.93), or pacemaker implantation (p=.21). The authors concluded that the early safety advantages of ViV should be weighed against a potential midterm benefit of redo-SAVR. The authors also noted that given the likely selection bias in individual studies, an adequately powered multicenter randomized trial with sufficiently long follow-up in patients with low-to-intermediate surgical risk is warranted.

Begun et al (2023) published a retrospective analysis of ViV TAVI compared to TAVI in a native valve using the Danish National Patient Registry from 2008 to 2020. A total of 6,070 patients (5,823 patients with native valve TAVI and 247 with ViV TAVI) were identified with a median age of 81 years. Patients with valve-in-valve-TAVI were younger but had a greater burden of cardiovascular comorbidities compared with patients with native-valve-TAVI. All-cause mortality was reported at 30 days, 1 year, and 5 years post-procedure with values of 2.4%, 9.7% and 28.7% in the ViV TAVI group and 2.7%, 10.3%, and 33.8% in the native TAVI group; no significant between group differences were observed for hazard ratios at any follow-up assessment. The cumulative 5-year risk of death was similar with 42.5% (95% CI, 34.2% to 50.6%) in patients with ViV TAVI and 44.8% (95%% CI, 43.2% to 46.4%) in patients with TAVI in a native valve. Overall, the number of rehospitalizations from any cause and from cardiovascular causes was not significantly lower in the group of patients with ViV TAVI compared with native-valve TAVI at 30 days, 1 year, and 5 years post procedure. The authors concluded TAVI in a failed surgical aortic prosthesis as compared to TAVI in a native valve, was not associated with significantly different short- and long-term mortality, suggesting that valve-in-valve-TAVI is a safe procedure.

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).

Zahr et al (2023) reported 1-year outcomes of the CLASP IID trial, which compared the safety and effectiveness of the PASCAL device (n=204) with the MitraClip device (n=96) for the treatment of MR in the full cohort of 300 patients. Prohibitive-risk patients with 3+/4+ degenerative mitral

regurgitation (DMR) were randomized 2:1 (PASCAL: MitraClip). The study population was well-balanced between the 2 groups, with the majority of participants in each group deemed to be at prohibitive surgical risk due to frailty. At 1-year follow-up, data were available for 91.5% and 94.3% of participants in the PASCAL and MitraClip groups, respectively. The primary safety endpoint, the proportion of patients experiencing a major adverse event at 30 days, was similar between the PASCAL (4.6%) and MitraClip (5.4%) groups (upper bound of 95% CI for between-group difference, 4.6%). Severe bleeding was the most common major adverse event in both groups (PASCAL: 3.6%; MitraClip: 2.2%), with 1 cardiovascular death (0.5%) in the PASCAL group and 2 (2.2%) in the MitraClip group. Freedom from major adverse events remained comparable between groups at 1 year (PASCAL: 84.7%; MitraClip: 88.3%; p=.471). The primary effectiveness endpoint, the proportion of patients with MR ≤2+ at 6 months, was achieved by 97.9% and 95.7% of patients in the PASCAL and MitraClip groups, respectively (absolute difference, 2.2%), meeting the prespecified noninferiority margin. At 1 year, MR reduction to ≤2+ was sustained in both groups (PASCAL: 95.8%; MitraClip: 93.8%), with no significant differences observed. Both groups experienced significant improvements in functional (NYHA functional class) and quality of life (Kansas City Cardiomyopathy Questionnaire Score, EQ-5D-5L, mean 6-minute walk distance) from baseline to 1 year (p<.05 for all), with no differences between groups. Study limitations included unblinded treatment allocation, the use of multiple generations of PASCAL and MitraClip devices, and loss to follow-up for time-to-event outcomes. The findings suggest that the PASCAL device is non-inferior to the MitraClip device for the reduction of MR severity and the rate of major adverse events at 1 year, consistent with the interim analysis.

Transcatheter Mitral Valve Implantation

Zhou et al (2023) conducted a systematic review and meta-analysis of transcatheter mitral valve in valve replacement (TMViVR) (n=1,464) versus redo surgical mitral valve replacement (rSMVR) (n=1,574) for patients who have had mitral bioprosthesis failure. Nine retrospective cohort studies were included in the analysis from a literature search through September 2022. TMViVR was associated with a lower reported in-hospital mortality than rSMVR (3.2% vs. 6.8%; odds ratio (OR), 0.44; 95% CI, 0.30 to 0.64; p<.001) with no observed heterogeneity. However, 30-day (OR, 0.65; 95% CI, 0.36 to 1.17; p=.15) and 1-year mortality (OR, 0.96; 95 %CI, 0.63 to 1.45; p=.84) did not differ significantly between treatment groups. The TMViVR group had a lower rate of reported stroke (OR, 0.44; 95% CI, 0.29 to 0.67), renal dysfunction (OR, 0.52; 95% CI, 0.37 to 0.75), vascular complications (OR, 0.58; 95% CI, 0.43 to 0.78), pacemaker implantation (OR, 0.23; 95% CI, 0.15 to 0.36), and exploration for bleeding (OR, 0.24; 95% CI, 0.06 to 0.96) than the rSMVR group. Conversely, redo SMVR had lower paravalvular leak (OR, 22.12; 95% CI, 2.81 to 174.16; P = 0.003). The authors concluded that the meta-analysis showed TMViVR in mitral prosthesis failure is associated with lower in-hospital mortality and lower occurrence of postoperative complications, except for paravalvular leak. TMViVR offers a viable alternative to the conventional redo surgery in selected patients. Limitations of this systematic review include that this was a study-level meta-analysis with a lack of patient- level data, additionally all the included studies were retrospective cohorts. Procedure bias or detection bias may have also influenced the outcomes of this meta-analysis. Thus, further studies, preferably in the form of randomized, large-scale, and strictly conducted trials, are needed to accurately evaluate TMViVR in patients with mitral prosthesis failure.

Ismayl et al (2023) published a meta-analysis comparing TMViVR (n=338) to rSMVR (n=369) for individuals with degenerated bioprosthetic mitral valves based on a literature search through September 2022. A total of six (6) observational studies with 707 patients were included, with a median follow-up of 2.7 years. Studies with potential overlap from the Nationwide Inpatient Sample and National Readmission Database were excluded from the analysis. Thirty-four patients (9.2%) in the TMViVR group received valve-in-ring rather than TMViVR and could not be separated for outcome assessment. The pooled risk of in-hospital mortality (OR, 0.52; 95% CI, 0.22 to 1.23; p=.14), 30-day mortality (OR 0.65; 95% CI, 0.36 to 1.17; p=.15), 1-year mortality (OR, 0.97, 95% CI, 0.63 to 1.49, p=.89), 2-year mortality (OR, 1.17; 95% CI, 0.65 to 2.13; p=.6) was similar between groups with low heterogeneity (I2= 0%). TMViVR had a lower risk of stroke (OR, 0.31; 95% CI, 0.11 to 0.88; p=.03), bleeding (OR, 0.21; 95% CI, 0.12 to 0.39; p<.00001), acute kidney injury (OR, 0.43; 95% CI, 0.22 to 0.84; p=.01), arrhythmias (OR, 0.17; 95% CI, 0.04 to 0.64; p=.009), permanent pacemaker insertion (OR, 0.18; 95% CI, 0.05 to 0.60; p=.005), and shorter hospital LOS than rSMVR. Limitations of the meta-analysis were that all the included studies were observational, with relatively small sample sizes, and the patient selection for each therapy was influenced by several factors, such as age, co-morbidities, surgical risk, and operator experience, which leads to inherent selection bias. Additionally, the included studies had a median follow-up period ranging from approximately 1 to 4.5 years, and further studies with longer follow-up are needed to better define the long-term outcomes. The authors concluded TMViVR was associated with better outcomes than rSMVR in patients with degenerated bioprosthetic mitral valves, including lower complication rates and shorter hospital LOS, with no significant difference in mortality rates. Large-scale randomized trials are needed to mitigate biases and confirm the findings.

Nasir et al (2024) conducted a systematic review and meta-analysis comparing TMViVR and rSMVR which included a total of eleven studies based on a literature search through April 2024. A total of 11,931 patients with degenerating bioprosthetic MV were included, of whom 3,592 underwent TMViVR and 8,263 underwent rSMVR. All of the studies included were retrospective. The mean age of patients undergoing TMViVR (75 yrs) was higher than the ones undergoing rSMVR (66 yrs). Of the eleven included studies, two (2) studies used transapical (TA) approach exclusively, one (1) used transseptal (TS) approach, and eight (8) used either the TS or TA approach. When comparing TMViVR with rSMVR, no significant difference was found for 30-day mortality (P = 0.13) and 1-year mortality (P = 0.91), whereas patients in the TMViVR showed significantly reduced incidence of stroke (P < 0.00001), In-hospital mortality (P), bleeding complications (P = 0.003), AKI (P = 0.0006), arrhythmias (P = 0.01), LVOT obstruction (P = 0.04), and PPI (P < 0.00001). Furthermore, no significant difference was observed between either group when comparing vascular complications (P = 0.97), 2-year mortality (P = 0.60) and 3-year mortality. TMViVR was associated with a significant risk of paravalvular leakage (P = 0.008). The meta-analysis has limitations of the included studies being observational with small sample sizes which carries the potential selection bias. Although, TMViVR reduces the risk of complications associated with rSMVR, larger studies are imperative to reach conclusive results. The authors propose diversifying study designs, incorporating both observational and experimental studies, especially randomized controlled trials (RCTs).

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy of ViV replacement of mitral valves. Further results from prospective, RCTs are needed to determine

safety, efficacy, durability, and the ideal candidates for the procedure.

Transcatheter Mitral Valve Annuloplasty

Giallauria et al (2020) performed a meta-analysis of individual patient data from the REDUCE FMR, TITAN, and TITAN II studies (n = 209). The studies compared transcatheter mitral valve repair with the Carillon device to optimal medical therapy alone in patients with functional MR. Primary outcomes of interest were measures of MR severity, LV remodeling, New York Heart Association functional class and heart failure-related outcomes. Pooled analysis showed that, compared with control, CARILLON device improved MR grade in patients with functional MR; but no significant effect on left ventricular ejection fraction. NYHA functional status improved more with Carillon than with medical therapy alone. Heart failure-related hospitalizations occurred less frequently among Carillon recipients than among control group patients. REDUCE FMR was the only randomized trial included. TITAN and TITAN II studies were non-randomized, non-blinded, multi-center trials. Limitations include small sample sizes in all three (3) included studies and Carillion was not compared to other proven transcatheter or surgical treatments.

D'Amario D et al (2024) published a systematic review and meta-analysis comparing the different percutaneous mitral valve repair approaches. Eleven studies were included: eight (8) [N = 1662 patients, mean follow-up 294 days] compared MitraClip vs Pascal device, two (2) (N = 195 patients) MitraClip vs Carillon and one (1) study (N = 186 patients) evaluated MitraClip against Cardioband. The two (2) studies comparing MitraClip and Carillon were inconsistent in terms of both efficacy and safety outcomes. In one (1) included study, MitraClip demonstrated a greater reduction in MR than Carillon, as assessed by reduction in vena contracta. In contrast, the use of Carillon showed favorable atrial remodeling with reduced atrial volume during follow up, which conversely increased in the Mitraclip group. In the second study both devices reduced the extent of MR in terms of vena contracta. The implant success rate was higher with MitraClip (95.7% vs. 83.8%; P = 0.02), due to a higher amount of complications after Carillon deployment, mainly related to impingement of a main branch of the left circumflex artery, coronary sinus dissection or non-availability of a device suitable for the individual anatomy. The only clinical endpoint evaluated was all-cause death, whose incidence was higher in the MitraClip treated group at both 1 and 5 years (65.2% vs. 45.2% and 100% vs. 93.5%, respectively; P =0.01). Limitations included the studies were retrospective with a small number of patients enrolled and a moderate risk of bias.

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

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 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 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 (Kenny 2011). 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.

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 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.

Transcatheter Caval Valve Implantation

Badwan et al (2023) performed a meta-analysis of studies evaluating clinical outcomes after caval valve implantation (CAVI) for severe symptomatic tricuspid regurgitation. Fifteen studies were included, eight (8) of them were case reports series. A total of 142 patients who underwent CAVI were included with the mean age ranged from 73.2 to 79.5 years. The median follow-up duration ranged from 61 to 350 days. The success rate in all studies was >90%, with 4.2% (6 of 142) requiring open heart surgery within 48 hours for stent migration or valve dislocation. Heart failure hospitalization was reported in 22.8% (21 of 92) within 6 to 12 months. Short-term mortality (at 3-month follow-up) occurred in 20.9% (29 of 139) of patients after CAVI. Long-term mortality (at 6 to 12 months follow-up) was reported in 47.2% (43 of 91). The authors found that CAVI was associated with significant reductions in NYHA functional class and tricuspid regurgitation severity. Study limitations include small sample size, short-term follow-up, and dissimilar definitions of procedural success. Also, multiple CAVI systems are incorporated into the pooled analysis. While hemodynamic and functional improvements are encouraging, larger-scale prospective studies with longer follow-up are needed.

Dreger et al (2020) published the TRICAVAL prospective, open-label, single-center, randomized trial which compared the impact of a balloon-expandable transcatheter valve into the inferior vena cava (CAVI) on exercise capacity with optimal medical therapy in patients with severe tricuspid regurgitation and high surgical risk. Twenty-eight patients were randomized to optimal medical therapy (n = 14) or CAVI (n = 14). The primary endpoint was maximal oxygen uptake at three (3) months follow-up. Secondary endpoints included the six-minute walk test, NYHA functional class, NT-proBNP levels, right heart function, unscheduled heart failure hospitalization, and quality of life. Patients underwent follow-up examinations one (1), three (3), six (6), and twelve months after randomization. Maximal oxygen uptake did not change significantly in either group after three (3) months and there was no difference between the medical therapy and CAVI groups (-0.1±1.8 ml·kg-1·min-1 vs -1.0±1.6 ml·kg-1·min-1, p=0.4995). Compared to baseline, CAVI improved NYHA class, dyspnea, and quality of life after three (3) months. However, there were no statistically significant differences in the secondary endpoints between the groups. Four (4) periprocedural complications occurred after CAVI, resulting in open heart surgery. CAVI did not result in a superior functional outcome compared to optimal medical therapy. Due to an unexpectedly high rate of valve dislocations, the study was stopped for safety reasons.

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.

Zahid et al (2023) conducted a meta-analysis evaluating the safety and efficacy of TAVI with cerebral embolic protection (CEP) devices versus TAVI alone. Six RCTs and 5 observational cohort studies with a total of 125,267 individuals with severe aortic stenosis who underwent TAVI with (n= 13,453) CEP or without (n=111,814) were included for review. The rate of major adverse cardiac events (OR, 0.75; 95% CI, 0.70 to 0.81; p<.01), mortality (OR, 0.65; 95% CI, 0.76 to 0.93; p<.01), and stroke (OR 0.84, 95% CI, 0.76 to 0.93; p<.01) was significantly lower in patients who had TAVI with CEP compared to TAVI with no CEP at 30 days follow-up. No significant differences were observed in the rate of vascular complications, acute kidney injury, or major or life-threatening bleeding between groups. Estimates of heterogeneity for these analyses were not reported. A stratified analysis by device found that the rate of MACE was significantly lower in patients who had TAVI with the Sentinel device (OR, 0.74, 95% CI 0.66 to 0.82; p<0.01) but not different for other devices (Triguard or Embrella) compared to TAVI with no CEP.

PROFESSIONAL GUIDELINE(S)

Transcatheter Aortic Valve Implantation or Replacement

In June 2019, the National Institute for Health and Care Excellence (NICE) 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 (Otto 2021). 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

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 (Otto 2021) 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. 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.)

AHA/ACC/HFSA Guideline for the Management of Heart Failure (Heidenreich 2022) state optimization of GDMT can improve secondary MR associated with LV dysfunction and obviate the need for intervention. Therefore, optimizing GDMT and reassessing MR before MV interventions are important. Patients with persistent severe secondary MR despite GDMT may benefit from either surgical or transcatheter repair, depending on clinical scenario. Thus, patient-centric conversation with a multidisciplinary cardiovascular team that includes a cardiologist with expertise in HF is essential when considering MV intervention. Specifically, transcatheter edge-to-edge MV repair 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.

Transcatheter Mitral Valve Implantation

In September of 2021, the National Institute for Health and Care Excellence (NICE) published interventional procedures guidance on transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis. The guidance states "evidence on the safety of transapical transcatheter mitral valve-in-valve implantation for a failed surgically implanted mitral valve bioprosthesis is adequate and shows some serious but well-recognized complications. Evidence on its efficacy is limited in quality. So, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."

The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) published guidelines for the management of valvular heart disease (Vahanian 2022). They state in bioprosthetic heart valve failure, transcatheter valve-in-valve implantation in the mitral

position may be considered in selected patients at high risk for surgical re-intervention (Class IIB, level of evidence B).

Transcatheter Mitral Valve Annuloplasty

Transcatheter mitral valve annuloplasty is not currently addressed in professional guidelines.

Transcatheter Pulmonary Valve Implantation

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 (Otto 2021).

The ACC/AHA 2018 Guidelines for the Management of Adults with Congenital Heart Disease (Stout 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

In July 2022, the National Institute for Health and Care Excellence (NICE) published interventional procedure guidance regarding Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation. The guidance recommendation is that "for people with severe and symptomatic tricuspid regurgitation, evidence on the efficacy of transcatheter tricuspid valve leaflet repair is limited in quantity and quality. Evidence on its safety shows there are serious but well-recognized complications. Therefore, for these people, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. For people with mild or moderate tricuspid regurgitation, evidence on the safety and efficacy of transcatheter tricuspid valve leaflet repair is inadequate in quantity and quality. Therefore, for these people, this procedure should only be used in the context of research."

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."

Transcatheter Caval Valve Implantation

In August 2024, the National Institute for Health and Care Excellence (NICE) published interventional procedure guidance on caval valve implantation for tricuspid regurgitation. The guidance states "more research is needed on caval valve implantation for tricuspid regurgitation in adults. The procedure should only be done as part of a formal study. There is very limited short- and long-term

evidence on the efficacy and safety of this procedure. Also, the evidence comes from studies that used different techniques to do the procedure and varied in the number and type of implants used. It is also unclear who would benefit from this procedure."

Cerebral Embolic Protection Device

Cerebral embolic protection devices are not currently addressed in professional guidelines.

REGULATORY STATUS

Transcatheter Aortic Valve Implantation or Replacement

The U.S. Food and Drug Administration (FDA) has approved the following devices:

I. Edwards SAPIEN Transcatheter Heart Valve System (Edwards Lifesciences) (November 2011)
   - A. Edwards SAPIEN Transcatheter Heart Valve (October 2012)
   - B. Edwards SAPIEN XT Transcatheter Heart Valve (July 2014)
   - C. SAPIEN 3 THV System (June 2015)
   - D. SAPIEN 3 Ultra THV System (December 2018)* The FDA issued a recall August 2019 due to reports of burst balloons causing difficulty retrieving the device into the sheath.

II. Medtronic CoreValve System (Medtronic, Inc.) (January 2014)
   - A. Medtronic CoreValve Evolut R System (June 2015)
   - B. Medtronic CoreValve Evolut PRO System (March 2017)
   - C. Medtronic CoreValve Evolut PRO+ System (August 2019)
   - D. Medtronic Evolut™ FX System (August 2021)

III. LOTUS Edge Valve System (Boston Scientific Corporation) (April 2019)* Boston Scientific Corporation announced a global, voluntary recall of all unused inventory of the LOTUS devices in January 2021. There are no safety concerns for patients who have the LOTUS device implanted. The recall was due to issues with the product delivery system. The LOTUS product has subsequently been retired.

IV. Portico with FlexNav (Abbott Medical) (September 2021)

V. Navitor Transcatheter Aortic Valve Implantation System with FlexNav (Abbott Medical) October 2023

Transcatheter Mitral Valve Repair

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."

In September 2022, the FDA approved the PASCAL Precision Transcatheter Valve Repair System through the premarket approval process for treatment of "significant, symptomatic mitral regurgitation (MR ≥3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team."

Transcatheter Mitral Valve Implantation

In June 2017, the Edwards SAPIEN 3 Transcatheter Heart Valve received FDA approval through the premarket approval process for transcatheter mitral valve-in-valve replacement (TMViVR) for the treatment of patients with a "failing surgical bioprosthetic mitral valve who have been determined to be at high or greater risk for open-heart surgery by a heart team." In May of 2024, the Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve received expanded FDA approvals for mitral ViV implantation in individuals with symptomatic heart disease due to a failing surgical bioprosthetic mitral valve (stenosed, insufficient, or combined) who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 4% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Transcatheter Mitral Valve Annuloplasty

Transcatheter mitral valve annuloplasty devices have not received FDA approval currently.

Transcatheter Pulmonary Valve Implantation

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).

On February 29, 2016, the Edwards SAPIEN XT Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) 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."

In March 2021, the Medtronic Harmony Transcatheter Pulmonary Valve (TPV) System was the first transcatheter valve system to be FDA-approved 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

In February 2024, Edwards Lifesciences' EVOQUE Tricuspid Valve Replacement System was granted FDA Breakthrough Device Designation. The system was studied and continues to be studied via the TRISCEND II trial. The FDA approval states, "Long-term durability has not been established for the EVOQUE valve. Regular medical follow-up is advised to evaluate EVOQUE valve performance."

Transcatheter Caval Valve Implantation

Transcatheter caval valve devices have not received FDA approval currently.

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 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).

The U.S. Food and Drug Administration (FDA) regulates transcatheter heart valves as medical devices. All transcatheter heart valves including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 6]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls and Early Alerts | FDA [accessed 2026 Mar 6]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0345T	Transcatheter mitral valve repair percutaneous approach via the coronary sinus

Code	Description
0483T (E/I)	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
0544T (E/I)	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
0805T (E/I)	Transcatheter superior and inferior vena cava prosthetic valve implantation (i.e., caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T (E/I)	Transcatheter superior and inferior vena cava prosthetic valve implantation (i.e., caval valve implantation [CAVI]); open femoral vein approach
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)

Code	Description
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy)
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
33369	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)
33370 (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	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure)
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

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HCPCS Codes

Code	Description
C1884 (E/I)	Embolization protective system

ICD10 Codes

Code	Description
I05.0-I05.9	Rheumatic mitral valve diseases
I06.0-I06.9	Rheumatic aortic valve diseases
I08.0-I08.9	Multiple valve diseases
I34.0-I34.9	Nonrheumatic mitral valve disorders
I35.0-I35.9	Nonrheumatic aortic valve disorders
I37.0-I37.9	Nonrheumatic pulmonary valve insufficiency
I50.1-I50.9	Heart Failure
I97.0	Intraoperative and postprocedural complications and disorders of circulatory system, not elsewhere classified – Postcardiotomy syndrome
I97.110	Postprocedural cardiac insufficiency following cardiac surgery
I97.130	Postprocedural heart failure following cardiac surgery
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
Q21.3	Tetralogy of Fallot
Q22.0-Q22.3	Congenital malformations of pulmonary valves
Q23.0-Q23.3; Q23.88; Q23.9	Congenital malformations of aortic and mitral valves
T82.01xA-T82.09xS	Mechanical complication of heart valve prosthesis
T82.221A-782.228S	Mechanical complication of biological heart valve graft
T82.857A-T82.857S	Stenosis of other cardiac prosthetic devices, implants, and grafts
T82.897A-T82.897S	Other specified complication of cardiac prosthetic devices, implants, and grafts
Z95.2-Z95.4	Presence of heart valves [implants and grafts]

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Wolfrum M, et al. Cerebral embolic protection during transcatheter aortic valve replacement: a systematic review and meta-analysis of propensity score matched and randomized controlled trials using the Sentinel cerebral embolic protection device. BMC Cardiovasc Disord. 2023 Jun;23(1):306.

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32) [accessed 2026 Mar 2]

Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) [accessed 2026 Mar 2]

Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) (NCD 20.38) [accessed 2026 Mar 2]

Transcatheter Tricuspid Valve Replacement (TTVR) (NCD 20.37) [accessed 2026 Mar 2]

Transcatheter Pulmonary Valve Implantation (TPVI) is not addressed in National or Local Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date