Transcatheter Heart Valve Procedures for Mitral or Tricuspid Valve Disorders

Effective: June 13, 2025

Next Review: June 2025
Last Review: June 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Conventional treatment of heart valve disorders includes surgical repair or replacement, which require open-heart surgery using cardiopulmonary bypass. Transcatheter (percutaneous or catheter-based) valve procedures use a catheter to access the heart and heart valves without the need for open-heart surgery and cardiopulmonary bypass. During the procedure, a compressed artificial heart valve or bioprosthetic valve is implanted.

MEDICAL POLICY CRITERIA

Note: This policy does not address mitral valve transcatheter edge-to-edge repair.

I. Transcatheter mitral valve replacement of a degenerated bioprosthetic valve (valve-in-valve) may be considered **medically necessary** when both of the following criteria are met (A. – B.):

   A. The device is approved by the U.S. Food and Drug Administration; and

   B. Patient has a failed (stenosed, insufficient, and/or combined) previous surgical bioprosthetic valve.

II. Transcatheter mitral valve replacement is considered **investigational** when Criterion I. is not met.

III. The following transcatheter heart valve procedures are considered **investigational**:

A. Transcatheter mitral valve replacement for native mitral valve disease

B. Transapical mitral valve repair with placement of artificial chordae tendinae

C. Transcatheter mitral valve annuloplasty reconstruction

D. Percutaneous transcatheter tricuspid valve repair

E. Transcatheter tricuspid valve annulus reconstruction

F. Transcatheter tricuspid valve replacement

G. Caval valve implantation

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Documentation that confirms the presence of a failing previously placed bioprosthetic mitral valve
- The name of the valve system to be implanted

CROSS REFERENCES

1. Transcatheter Aortic Valve Implantation for Aortic Stenosis, Surgery Policy No. 201

BACKGROUND

HEART VALVE DISORDERS

The American Heart Association (AHA) and American College of Cardiology (ACC) recommend classifying valvular heart disease (VHD) by stages based on symptoms, valve anatomy, the severity of valve dysfunction, and the response of the ventricle and pulmonary circulation.[1] To evaluate patients with valvular heart disease, patient history and physical examination should be correlated with results of non-invasive testing (e.g., electrocardiogram (ECG), chest x-ray, and transthoracic echocardiogram). If there is discordance between physical examination and initial non-invasive testing, further non-invasive testing (e.g., computed tomography, cardiac magnetic resonance imaging, and stress testing) or invasive testing (e.g., transesophageal echocardiography or cardiac catheterization) may be considered to determine treatment.

The AHA/ACC classification of the progression of VHD includes four stages, A to D:

- Stage A (at risk) is defined as patients with risk factors for development of VHD.

- Stage B (progressive) is defined as patients with progressive VHD (mild to moderate severity and asymptomatic).
- Stage C (asymptomatic severe) is defined as:
    - Stage C1: symptomatic patients with severe VHD in whom the left ventricle (LV) or right ventricle (RV) remains compensated
    - Stage C2: asymptomatic patients with severe VHD with decompensation of the LV or RV
- Stage D (symptomatic severe) is defined as patients who have developed symptoms as a result of VHD.

Indications for intervention and periodic monitoring are dependent on 1) the presence or absence of symptoms, 2) the severity of VHD, 3) the response of the LV and/or RV to volume or pressure overload caused by VHD, and 4) the effects on the pulmonary or systemic circulation.

The purpose of valvular intervention is to improve symptoms, prolong survival, and minimize the risk of VHD-related complications, such as irreversible ventricular dysfunction, pulmonary hypertension, stroke, and atrial fibrillation (AF).

Mitral Regurgitation

Mitral regurgitation (MR) is the second most common valvular heart disease, occurring in 7% of people older than age 75 years 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 2 categories: primary (also called degenerative) and secondary (also called functional) MR. Primary MR results from a primary structural abnormality in the valve, which causes it to leak. This leak may result from a floppy leaflet (called prolapse) or a ruptured cord that caused the leaflet to detach partially (called 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 valve (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 U.S.

According to the American College of Cardiology, the treatment of choice for mitral regurgitation is transcatheter edge-to-edge repair (TEER), which is not addressed in this policy.[2] Surgical approaches to mitral regurgitation other than TEER have been suggested for people with anatomical barriers to TEER (e.g., coaptation gap $\geq$15mm, flail gap $\geq$10mm) who are not candidates for surgery. [2, 3] Interventions for mitral valve regurgitation addressed in this policy are transcatheter mitral valve replacement (TMVR), transapical mitral valve repair, and transcatheter mitral valve annuloplasty reconstruction (TMVAR).

Tricuspid Regurgitation

Severe tricuspid regurgitation (TR) presents with systemic fluid retention, leading to elevated jugular venous pressure, peripheral edema, and ascites; reduced intestinal absorption and anasarca; decreased cardiac reserve, resulting in exercise intolerance, dyspnea, and poor functional capacity; and decreased cardiac output, with progressive end-organ damage caused by a combination of end-organ venous congestion and underperfusion.[4] Many signs and symptoms of severe tricuspid regurgitation may initially respond to diuretics. However, reduced cardiac output and neurohormonal changes may cause liver (cardiohepatic) or kidney (cardiorenal) disease. Cardiohepatic syndrome increases bleeding risk and is a strong independent predictor of death or hospitalization for heart failure within one year of transcatheter tricuspid valve therapy. The prevalence of tricuspid regurgitation increases with age and may be up to four times higher in women. Other clinical predictors of severe tricuspid regurgitation include atrial fibrillation, elevated pulmonary artery systolic pressure, and increased left atrial size.

Management of TR is based upon the cause of TR, the presence and extent of symptoms and signs of heart failure (HF), the severity of TR, and the presence and extent of associated abnormalities, including pulmonary hypertension, tricuspid annular dilation, and other valve disease.[1] Management of severe TR includes medical therapy, counseling regarding pregnancy and physical activity, and consideration of tricuspid valve surgery. Management also includes evaluation and treatment of the underlying cause(s), which often includes other cardiovascular disorders, particularly mitral valve disease and/or HF. Medical therapy is the primary approach to management of severe TR in most patients, including loop diuretics and mineralocorticoid receptor antagonists.

Tricuspid valve surgery usually is performed at the time of surgery for left sided heart disease. Isolated tricuspid valve surgery is rarely performed with only 5,005 procedures over a ten-year period (2004 to 2013) nationally in the United States.[5] Indications for tricuspid valve surgery depend upon whether surgery for left-sided (mitral or aortic) valve disease is indicated. Tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations in patients with signs and symptoms of right-sided HF and severe isolated secondary TR attributable to annular dilation who are poorly responsive to medical therapy (in the absence of pulmonary hypertension or left-sided disease).[6]

Although comparative data are limited, tricuspid valve repair is generally preferred to tricuspid valve replacement, with valve replacement performed only when repair is not feasible. Advantages of tricuspid valve repair include technical ease and speed of operation. On the other hand, the rate of recurrent TR following tricuspid repair is substantial and the mortality risk of tricuspid valve reoperation is high.

Another approach to TR is heterotropic caval valve implantation (CAVI). The goal of CAVI is not to reduce tricuspid regurgitation, but to reduce systemic venous congestion, thereby alleviating the resultant effects on the liver, kidney, and gastrointestinal tract.[7] The concept centers in the heterotopic placement of a valve in the inferior vena cava (IVC) and another in the superior vena cava (SVC), at the cavo-atrial junctions. At the chronic phase, reduction in peripheral congestion decreases the risk of cardiac cirrhosis, also reducing right heart overload promoting a degree of reverse RV remodeling, and possibly even reductions in tricuspid annular dilatation, and thus the severity of TR in some cases.[8] By alleviating caval regurgitant volume CAVI may also ultimately increase RV stroke volume and improve cardiac output.

REGULATORY STATUS

Multiple manufacturers have transcatheter heart valve devices with FDA approval. FDA-approved transcatheter heart valve devices include but are not limited to the following:

- The SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System received premarket approval from the United States Food and Drug Administration on September 9, 2020.[9] This device is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve, a surgical bioprosthetic mitral valve, or a native mitral valve with an annuloplasty ring who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).
    - The Edwards SAPIEN 3 is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, a trileaflet bovine pericardial tissue valve, a polyethylene terephthalate (PET) internal fabric skirt, and a PET external sealing skirt for reduction of paravalvular regurgitation.
    - Product code: NPU

- The EVOQUE Tricuspid Valve Replacement System (Edwards) received premarket approval from the United States Food and Drug Administration on February 1, 2024.[10] This device is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, for whom tricuspid valve replacement is deemed appropriate by a heart team.
    - The EVOQUE system consists of an artificial tricuspid valve (EVOQUE valve) and a delivery catheter. The valve is made of bovine tissue attached to a self-expanding nickel-titanium frame for support.
    - Product code: NPW

- The TriClip G4 System (Abbott Medical) received United States Food and Drug Administration premarket approval on February 13, 2024 for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.[11]
    - The TriClip G4 System is designed to repair the native tricuspid valve without open heart surgery by grasping and bringing together (coapting) the tricuspid valve leaflets to reduce tricuspid regurgitation (TR). The device is composed of the TriClip Steerable Guide Catheter (SGC), the TriClip G4 Delivery System (TDS), and Accessories.
    - Product code: NPS

EVIDENCE SUMMARY

TRANSCATHETER MITRAL VALVE REPLACEMENT

Native mitral valve disease

Systematic Reviews

Ahmed (2023) published a systematic review which examined the Tendyne Transcatheter Mitral Valve System for transcatheter mitral valve replacement (TMVR) over the last 10 years.[12] 26 articles were included with a total of 319 patients, including 192 males and 127 females. Mitral annular calcification was reported in 107 patients. Preoperatively, mitral regurgitation grade one was identified in three patients, grade two was identified in five patients, and grades three to four were identified in 307 patients. Postoperatively, mitral regurgitation grade one was identified in 12 patients, grade two was identified in three patients, and grade four was identified in one patient, overall, resulting in a significant mitral regurgitation improvement. Technical success was achieved in 309 patients. Follow-up periods varied from days before discharge to six years and at the end of follow up, 79 patients died, including 52 due to cardiovascular causes. The authors concluded that further research is needed to with longer duration follow-up phases and randomized controlled trials.

Del Val (2019) conducted a systematic review of TMVR for the treatment of severe mitral regurgitation in patients with high surgical risk.[13] A total of 16 studies with 308 total patients met inclusion criteria. The etiology of mitral regurgitation was secondary or mixed in 87.1% of patients, and 81.5% of the patients were in New York Heart Association (NYHA) class III or IV. The procedure was conducted via the transapical approach in 81.5% of patients. Devices used included the AltaValve, Caisson TMVR, CardAQ Valve, CardioValve, Fortis, HighLife, Interpid TMVR, MValve, Tiara, Sapien M3, and Tendyne. Technical success was 91.7%, postprocedural mean transmitral gradient was 3.5 mm Hg, and 1.5% of cases presented residual postprocedure moderate to severe mitral regurgitation. Procedural and all-cause 30-day mortality were 4.6% and 13.6%, respectively. Four percent of patients were converted to open heart surgery. Left ventricular outflow obstruction was reported in 0.3% of patients, respectively. All-cause and cardiovascular-related mortality rates were 27.6% and 23.3%, respectively, after a mean follow-up of 10 (range: 3 to 24) months.

Nonrandomized Studies

Ludwig (2020) reported outcomes of seven patients treated with the Tendyne and four patients treated with the Tiara TMVR systems.[14] Etiologies included primary, secondary, and mixed mitral regurgitation. All patients were symptomatic (NYHA III/IV) and at high surgical risk (logEuroSCORE II 8.1% [4.0, 17.4]). All patients achieved technical success. Following treatment, all patients had no or only trace mitral regurgitation. Overall mortality at three and six months was 10.0% and 22.2%, respectively. This study is limited by small sample size and lack of a comparison group.

Webb (2020) published outcomes of 14 patients treated with the EVOQUE transseptal TMVR system for moderate or greater mitral regurgitation.[15] One patient was converted to surgery and the rest achieved technical success. Adverse events within 30 days included one noncardiovascular mortality (7.1%), two paravalvular leaks (14.3%), and two strokes (14.3%). There were no myocardial infarctions or rehospitalizations. At 30 days, mitral regurgitation was mild or less in all implanted patients, with no mitral regurgitation in 10 patients (83.3%). The NYHA functional class improved to II or lower in in patients (81.8%). This study is limited by small sample size and lack of a comparison group.

Bioprosthetic valve failure

Systematic Reviews

Ismayl (2023) published a systematic review of six observational studies comprising 707 patients with bioprosthetic mitral valve (MV) degeneration to compare outcomes of valve-in-valve transcatheter mitral valve replacement (ViV-TMVR) to redo surgical mitral valve replacement (redo-SMVR).[16] The reviewers employed a random-effects model to calculate odds ratios (OR) with 95% confidence intervals (CI). Median follow-up time was 2.7 years. The studies included in this review were retrospective and observational in nature, and while propensity matching was used to reduce selection bias, patients in the ViV-TMVR group were older and had more co-morbidities than those in the redo-SMVR group. No differences in , mortality rate primary outcomes were identified: in-hospital mortality (OR 0.52, 95% CI 0.22 to 1.23, p=0.14), 30-day mortality (OR 0.65, 95% CI 0.36 to 1.17, p=0.15), one-year mortality (OR 0.97, 95% CI 0.63 to 1.49, p=0.89), and two-year mortality (OR 1.17, 95% CI 0.65 to 2.13, p=0.60). ViV-TMVR was associated with significantly lower risks of stroke, bleeding, acute kidney injury, arrhythmias, and permanent pacemaker implantation, as well as shorter hospital length of stay. The reviewers reported that overall heterogeneity among studies was low and found no evidence of publication bias. The review authors concluded that ViV-TMVR was associated with better outcomes than redo-SMVR in patients with degenerated bioprosthetic mitral valve, including lower complication rates and shorter hospital length of stay, with no significant difference in mortality rates. The studies included in this meta-analysis have multiple limitations. All included studies had an observational design and multiple studies had relatively small sample sizes (range 51 to 215). Patient selection for these therapies is influenced by age, co-morbidities, surgical risk, and operator experience which creates inherent selection bias. All studies had a median follow-up time of one to 4.5 years, and the review authors concluded that additional studies with longer term follow-up are needed to better assess treatment durability, long-term outcomes, and application of ViV-TMVR to patients at lower surgical risk.

Zhou (2022) performed a systematic review and meta-analysis of the same studies included in Ismayl (2023)[16], with an additional three retrospective cohorts.[17] This review found that TMVR was associated with lower in-hospital mortality (OR 0.44; 95% CI: 0.30-0.64; p<0.001) but the differences in 30-day mortality (OR 0.65; 95% CI: 0.36-1.17; P=0.15) and one-year mortality were not significant (OR 0.96; 95% CI: 0.63-1.45; p=0.84). TMVR was also associated with fewer postoperative strokes (OR 0.44; 95% CI 0.29-0.67, p=0.0001), lower risk of renal dysfunction (OR 0.52; 95% CI: 0.37-0.75, p=0.0003), a lower vascular complication rate (OR 0.58; 95% CI 0.43-0.78, p=0.004), fewer pacemaker implantations (OR 0.23; 95% CI: 0.15-0.36, p< 0.00001), and decreased risk of exploration for bleeding (OR 0.24; 95% CI: 0.06-0.96, p=0.04). However, the rate of postoperative paravalvular leak was higher in the TMVR group (OR 22.12, 95% CI: 2.81-174.16, p=0.003). The difference in mitral valve gradient was not significant (p=0.87). Heterogeneity between the studies was low (0%). The study limitations include the possibility of selection bias due to lack of randomization, the retrospective design of the studies and short follow-up times. The authors conclude that there is evidence that TMVR is associated with fewer surgical complications and can reduce in-hospital mortality compared to SMVR but large randomized studies are needed to confirm the review findings.

Non-randomized studies

Simard (2022) published the five-year outcomes of patients with degenerated mitral valve prostheses treated with TMVR or redo surgical mitral valve replacement (SMVR).[18] The cohort included 86 patients (40%) treated with TMVR (75 [87%] valve-in-valve and 11 [13%] valve-in-ring) and 129 patients (60%) who underwent SMVR. The TMVR cohort was older (p<0.0001), more symptomatic (p=0.0003) and had more chronic lung disease (p=0.02), worse

renal function (p=0.02), and higher right ventricular systolic pressures (p<0.0001). 30 day mortality was lower with TMVR versus SMVR (2.4% vs. 10.2%, odds ratio [OR] 4.69 [95% CI 1.25 to 30.5], p=0.04) with probability of mortality at one, two, and five years being 14.7% versus 17.5%, 24.5% versus 20.7%, and 49.9% versus 34.0%, respectively. Mode of prosthesis degeneration, baseline hemodynamics, and valve selection did not appreciably impact outcomes. The authors concluded that TMVR for degenerated mitral prostheses is associated with better early survival compared to SMVR despite a greater burden of comorbidities. In contrast, five-year survival rates appear more favorable with SMVR, which may reflect the lower baseline risk of this population.

Zahid (2022) performed a retrospective analysis using the Nationwide Readmission Database on readmission outcomes from TMVR valve-in-valve replacement compared to surgery redo (SMVR) in 3,691 patients with a history of bioprosthetic mitral valve.[19] The researchers used a propensity-matched analysis to determine the adjusted odds ratio. After propensity matching 791 cases were TMVR and 841 were SMVR. The study found that the following were significantly different:

- All-cause in-hospital mortality was higher in the SMVR group (7.3% vs. 2.6%; p<0.01).
- Discharges to sites other than home were higher after SMVR despite the TMVR group having more co-morbidities (77.2% vs 46.1%; p<0.01).
- In-hospital complications: stroke, need for blood transfusion or pacemaker, and pneumonia were all higher with SMVR (each p<0.01).
- In-hospital cardiac arrest higher with SMVR (p=0.02).
- Hospital length of stay was longer with SMVR (15 days vs. 4 days; p<0.01).

Findings that were not significantly different:

- Mortality during episode of readmission at 30 days (p=0.36).
- All-cause readmission (p=0.57).
- Need for blood transfusion, stroke, vascular complication, pacemaker, or pneumonia at 30 days.
- Readmissions (p=0.13) and mortality (p=0.11) during hospitalization at 6 months.

The authors concluded that TMVR was associated with fewer in-hospital deaths and complications which indicate TMVR has superior short-term safety. TMVR is also associated with shorter LOS and higher discharge-to-home rates than SMVR. The similar readmission in-hospital mortality rates, and complications at 30 days and six-months indicate outcomes compared to SMVR. findings indicate that TMVR has similar overall safety and efficacy as SMVR. Limitations include that deaths outside the hospital were not captured in the data.

Section Summary

The evidence regarding transcatheter mitral valve replacement consists of systematic reviews and non-randomized studies. There is not enough research to show that transcatheter mitral valve replacement improves health outcomes for people with mitral regurgitation due to native valve disease. Available studies are limited by small sample sizes and lack of comparisons of transcatheter mitral valve replacement to other treatments.

There is enough evidence that transcatheter mitral valve replacement for failed bioprosthetic valves is associated with improved health outcomes, including fewer procedure-related

complications than open surgery (e.g., stroke, bleeding), possibly a lower rate of in-hospital mortality, with no difference in post-procedure outcomes at 30 days and one-year.

TRANSAPICAL MITRAL VALVE REPAIR WITH PLACEMENT OF ARTIFICIAL CHORDAE TENDINAE

Systematic Reviews

Ahmed published a systematic review of six studies of mitral valve repair using the NeoChord DS1000 device, which is inserted into the beating heart to place artificial chordae tendinae.[20] The studies involved 249 patients who were classified as NYHA functional class I-IV, but the majority (225) were class II or III, and 243 had severe MR. Intraoperative events included arrhythmia in six patients (2.4%) and significant bleeding in eight patients (3.2%). There were no intraoperative deaths. The most frequent post-operative complications were pleural effusion (34.5%), atrial fibrillation (19.7%), acute kidney injury (5.6%), and would dehiscence (5.6%). The post-operative mortality rate was 1.6%. The review was limited by the retrospective design of the included studies and small sample sizes. The authors state larger study results are expected in 2025 and 2027.

Section summary

There is not enough research to show that transapical mitral valve repair with placement of artificial chordae tendinae improves health outcomes of people with mitral valve regurgitation. Prospective studies that compare transapical mitral valve repair with placement of artificial chordae tendinae to other treatments are needed.

TRANSCATHETER MITRAL VALVE ANNULOPLASTY RECONSTRUCTION (TMVAR)

Randomized Studies

Several indirect annuloplasty devices, including the Carillon Mitral Contour System (Cardiac Dimension) and the Monarc device (Edwards Lifesciences), have been evaluated. Witte (2019) published the REDUCE-functional mitral regurgitation (FMR) study, a double-blind, randomized sham-controlled proof-of-concept study that evaluated the effects of the Carillon mitral annuloplasty device on FMR severity and left ventricular (LV) remodeling in people with FMR despite medical therapy.[21] The primary endpoint was change in mitral regurgitant volume at one year compared to baseline between the treatment group and sham control group. Secondary safety and efficacy endpoints included major adverse events, changes in LV end-systolic and end-diastolic volumes, changes in 6-minute walk distance and NYHA functional class as compared to baseline at 12 months. One hundred and twenty subjects were randomized in a 3:1 treatment to control ratio (87 to treatment and 33 to sham control). Device implantation was not carried out in 14 patients. Two deaths occurred within 30 days in implanted patients, and one was judged to be possibly related to the procedure. At 12-months, there was 10.4 ml/beat difference in mean mitral regurgitant volume between the two groups (95% confidence interval [CI]: 0.1 to 20.7; -7.1ml/beat [95% CI -11.7 to -2.5] vs. 3.3 ml/beat [95% CI: -5.98 to 12.62]; p = 0.049). The treatment group demonstrated a median 22.4% decrease in mitral regurgitant volume (MRV), while the control group had a 1.5% increase in MRV. 12-month improvement in FMR was greater in the treatment arm (50%) than the control arm (20%; p=0.02). There were significant decreases in LV end-diastolic volume (p=0.03) and end-systolic volume (p=0.04) in the treatment arm whereas the control arm had increases in both measures. The treatment arm showed significant improvement in 6-minute walk test

(p=0.002) from baseline while the controls did not (p=0.29). The treatment group also showed improvement in their NYHA classification (p=0.002) while the control group did not (p=0.29). There were no significant differences in major adverse events or heart failure hospitalizations. Paired echocardiography data to assess mitral regurgitation severity was available for only 57% of subjects. Other limitations of the study include that it was not powered to show between group differences. The authors note that while the study achieved its primary endpoint, further research is needed.

Khan (2021) published follow-up data from REDUCE-FMR that compared functional outcomes through one year in participants with moderate-to-severe FMR treated with the Carillon mitral annuloplasty device or sham control.[22] Of 83 subjects from the REDUCE-FMR (62 from treatment arm and 21 from sham control arm). The study found that the treatment arm had higher mean improvement in 6-minute walk distance (24m vs. 9m), Kansas City Cardiomyopathy Questionnaire (KCCQ) score (12 vs. 5), and ≥1 NYHA class change (48% vs. 33%), and freedom from hospitalization or death (60% vs 48%) compared to the control group. The study notes that while the study findings suggest improvement with the Carillon device, they are considered exploratory, not confirmatory because the study is inadequately powered. Further studies are needed to determine actual benefit and long-term outcomes beyond one year.

Section Summary

There is not enough research to show that TMVAR improves health outcomes for people with mitral valve regurgitation. Additional research to determine TMVAR efficacy and long-term outcomes is needed.

PERCUTANEOUS TRANSCATHETER TRICUSPID VALVE REPAIR

Systematic Reviews

Rehan (2023) conducted a systematic review and meta-analysis that assessed tricuspid regurgitation severity and additional echocardiographic outcomes in patients undergoing transcatheter edge-to-edge repair with the TriClip, MitraClip, and PASCAL devices.[23] The review included one RCT and 14 observational studies of patients with moderate-to-severe tricuspid regurgitation (grade III to V). Outcomes included echocardiographic and quality of life determining outcomes such as improvement in TR severity grade ≥3, New York Heart Association (NYHA) functional class ≥3, procedural success, 6-minute walking distance (6MWD), and adverse outcomes. Analysis revealed a substantial reduction in tricuspid regurgitation volume (p<0.00001), tricuspid regurgitation grading (p<0.00001), tricuspid annular diameter (p<0.00001), proximal isovelocity surface area radius (p<0.00001), effective regurgitant orifice area (p<0.00001), and improvement in NYHA class (p<0.00001) at 30 days from baseline, post procedurally. A significant increase in 6MWD at one year (p=0.001) was also recorded. No significant differences in left ventricular ejection fraction (p=0.87), fractional area change (p=0.37), or tricuspid annular plane systolic excursion (p=0.76) were observed. The review authors concluded that large scale RCTs comparing the tricuspid transcatheter edge-to-edge repair (TTEER) devices are needed to strengthen the present findings.

Montalto (2020) published a systematic review and meta-analysis of the feasibility, efficacy, and clinical outcomes of transcatheter repair of tricuspid regurgitation.[24] Studies were included if enrolled patients had at least moderate tricuspid regurgitation, determined by a semi-quantitative method, and if at least one of the primary outcomes had a minimum follow-

up of 30 days. Case reports, letters, and studies which did not clearly report the numbers and rates of alive patients at follow-up were excluded. Seven studies of 454 patients were included in the pooled analysis. 95% of patients had at least severe tricuspid regurgitation, and 91% were in NYHA functional class III or IV. Successful implantation occurred in 86% of patients. At the longest follow-up (mean=265 days), 9% of patients had died. Compared to the pre-treatment baseline, a significantly lower proportion of patients had at least severe tricuspid regurgitation (relative risk, 0.38; 95% confidence interval (CI) 0.20 to 0.70; p=0.004) and were in NYHA functional class III or IV (relative risk, 0.23; 95% CI 0.20 to 0.30; p=0.001). Increases in 6MWD were observed (mean difference +64.6 minutes; p<0.001). Significant reductions in tricuspid valve annular diameter were also reported (mean difference -3 millimeters; p<0.001). Left and right ventricular function were not significantly altered.

Randomized Controlled Trials

Sorajja (2023) published an RCT which evaluated the safety and efficacy of percutaneous (TTEER) for the treatment of severe tricuspid regurgitation at 65 centers in the United States, Canada, and Europe.[25] 350 patients with symptomatic severe tricuspid regurgitation were randomly assigned in a 1:1 ratio to receive either TTEER (n=175) or a medical therapy control (n=175). Mean age was 78 years, and 54.9% of patients were women. The primary composite end point included death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and an improvement in quality of life as measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ), with an improvement defined as an increase of at least 15 points in the KCCQ score (range, 0 to 100, with higher scores indicating better quality of life) at one-year follow-up. Primary endpoint results favored the TTEER group (win ratio, 1.48; 95% confidence interval, 1.06 to 2.13; p=0.02). The incidence of death or tricuspid-valve surgery and the rate of hospitalization for heart failure were similar between the two groups. The KCCQ quality-of-life score changed by a mean (±SD) of 12.3±1.8 points in the TTEER group, as compared with 0.6±1.8 points in the control group (p<0.001). At 30 days, 87.0% of the patients in the TTEER group and 4.8% of those in the control group had tricuspid regurgitation of no greater than moderate severity (p<0.001). TTEER was found to be safe; 98.3% of the patients who underwent the procedure were free from major adverse events at 30 days. This study is limited by lack of long-term outcomes beyond one year.

Nonrandomized Studies

Lurz (2024) published one-year outcomes from the bRIGHT study ((An Observational Real-World Study Evaluating Severe Tricuspid Regurgitation Patients Treated With the Abbott TriClip™ Device).[26] The bRIGHT study is a postapproval, open-label, single-arm, prospective, observational registry study being conducted at 26 sites in Europe to assess echocardiographic outcomes of tricuspid transcatheter edge-to-edge repair with the TriClip system. Enrolled subjects were elderly (79±7 years) with significant comorbidities. 88% of patients had baseline massive or torrential tricuspid regurgitation, and 80% percent of subjects were in NYHA class III/ IV. Tricuspid regurgitation was reduced to moderate or less in 81% of patients at one-year post-treatment. Significant improvements in NYHA class (21% to 75% I/II, p<0.0001) and KCCQ score (19±26-point improvement, p<0.0001) were observed. One-year mortality was significantly lower in subjects who achieved moderate or lower tricuspid regurgitation at 30 days. However, there was no difference in mortality among subjects that achieved moderate, mild, or trace tricuspid regurgitation at 30 days. In addition to tricuspid regurgitation reduction at 30 days, baseline serum creatinine and baseline right ventricular tricuspid annular plane systolic excursion (RV TAPSE) were independently associated with

mortality at one year (odds ratio [OR]: 2.169, 95% CI 1.494 to 3.147, p<0.0001; OR: 0.636, 95% CI 0.415 to 0.974, p=0.0375). Mortality was not associated with baseline TR grade, nor with center volume.

Lurz (2023) published short-term outcomes from the bRIGHT study.[27] Participant mean age was 79± 7 years, and participants had significant comorbidities. 88% of participants had baseline massive or torrential tricuspid regurgitation, and 80% were in NYHA functional class III or IV. Tricuspid regurgitation was reduced to less than or equal to moderate at 30 days post-implantation in 77% of participants. Associated significant improvements in NYHA functional class (I/II, 20% to 79%; p<0.0001) and KCCQ score (19 ± 23 points improvement; p<0.0001) were also observed at 30 days. 14 subjects (2.5%) experienced a major adverse event by day 30 (e.g., cardiovascular mortality, stroke, new onset renal failure, or non-elective cardiovascular surgery for device-related adverse event). This study is limited by lack of a comparison group and long-term follow-up.

Von Bardeleben (2023) published two-year outcomes from 85 participants in the TRILUMINATE trial, an ongoing international, multicenter, single-arm study evaluating safety and performance of tricuspid transcatheter edge-to-edge repair with the TriClip implant.[28] At year two, tricuspid regurgitation was reduced to moderate or less in 60% of subjects, and reduction of at least one grade was achieved in 85.4% of participants. Tricuspid regurgitation reduction was sustained in 75% of patients. Substantial improvements in 6MWD, NYHA functional class, and KCCQ score were sustained from 30 days to two years. The all-cause hospitalization rate decreased from 1.30 events per patient per year to 0.66 events per patient per year two years after the TriClip procedure, a 49% reduction (p<0.0001). This study is limited by lack of a comparison group and small sample size.

Arnold (2023) published results from the TRILUMINATE pivotal trial, a prospective, multicenter, randomized, open-label trial of tricuspid edge-to-edge transcatheter valve repair with the TriClip device in patients with severe symptomatic tricuspid regurgitation.[29] Eligible patients had severe, massive, or torrential tricuspid regurgitation confirmed by an independent echocardiography laboratory, NYHA functional class II to IVa symptoms, pulmonary artery systolic pressure less than 70 mm Hg, and no other cardiovascular conditions in need of interventional or surgical correction (e.g., severe mitral regurgitation). Participants were also on stable guideline-directed medical therapy for heart failure for at least 30 days. Mean participant age was 78± 7 years, and 45% of participants were men. 12% of participants had chronic lung disease. Participants were randomized to receive either tricuspid edge-to-edge transcatheter valve repair (n=169) or medical therapy only (n=163 participants). Health outcomes were assessed at baseline, one month, six months, and 12 months with KCCQ scores. Alive and well was defined as a KCCQ overall summary score greater than or equal to 60 and no decline from baseline greater than 10 points at one year. Compared with medical therapy, tricuspid edge-to-edge transcatheter valve repair significantly improved health status at one month (mean between group difference in KCCQ overall summary score 9.4 points; 95% CI, 5.3 to 13.4 points). A small, additional improvement occurred at one year (mean between-group difference 10.4 points; 95% CI, 6.3 to 14.6 points). Patients who received tricuspid edge-to-edge transcatheter valve repair were more likely to meet the alive and well criteria at one year compared to patients who received medical therapy (74.8% vs. 45.9%; p<0.001). This study is limited by susceptibility of patient-reported outcomes to bias due to lack of blinding, lack of assessment of clinical outcomes of death or heart failure hospitalization, and lack of long-term follow-up beyond one year.

Freixa (2022) published a retrospective multicenter study that collected data from all patients undergoing edge-to-edge tricuspid valve repair with the TriClip system in Spain between June 2020 and March 2021 (n=34 patients).[30] The primary endpoint was achievement of a tricuspid regurgitation reduction of at least one grade at discharge. 91% of patients had a history of atrial fibrillation, and one patient had a pacemaker lead. The primary endpoint was met in all patients. At three months, no mortality events occurred. 88% of patients were in New York Heart Association (NYHA) class less than or equal to two, and 80% had residual tricuspid regurgitation less than or equal to two. One patient experienced a partial clip detachment, which was stabilized with additional clips in the same procedure. This study is limited by small sample size and lack of long-term follow-up beyond three months.

Orban (2020) published an observational study which evaluated the effect of transcatheter edge-to-edge tricuspid valve repair (TTVR) for severe tricuspid regurgitation (TR) on hospitalization for heart failure (HHF) and HF-related endpoints.[31] Isolated TTVR was performed in 119 patients. Results were compared with those of 114 patients who underwent combined mitral and tricuspid valve repair. Procedural success with a reduction to moderate or less tricuspid regurgitation and no in-hospital death was achieved in 82% of patients. At a median follow-up of 360 days, a reduction to moderate or less tricuspid regurgitation was achieved in 72% of patients ($p<0.001$). TTVR reduced the annual rate of HHF by 22% (1.21 to 0.95 HHF per patient per year; $p=0.02$). Clinical improvement was also observed for NYHA functional class (patients in class II or lower: 9% to 67%; $p<0.001$), 6MWD (+39 m; $p=0.001$), and Minnesota Living with Heart Failure Questionnaire score (-6 points; $p=0.02$). N-terminal pro-B-type natriuretic peptide level decreased by 783 picograms per milliliter. Procedural success was associated with improved one-year survival (79% vs. 60%; $p=0.04$) and event-free-survival (death + first HHF: 67% vs. 40%; $p=0.001$). Transcatheter mitral and tricuspid valve repair-treated patients had comparable outcomes.

Nickenig (2017) published an observational study of safety and feasibility of transcatheter repair of chronic severe tricuspid regurgitation with the MitraClip system.[32] In addition, the effects on clinical symptoms were assessed. Patients with heart failure symptoms and severe tricuspid regurgitation, on optimal medical therapy, were treated with the MitraClip system. Safety was defined as periprocedural adverse events such as death, myocardial infarction, stroke, or cardiac tamponade. Feasibility was defined as successful implantation of one or more MitraClip devices and reduction of tricuspid regurgitation by at least one grade, after 30 days. 64 patients (mean age 76.6±10 years), deemed unsuitable for surgery, underwent MitraClip treatment for chronic, severe tricuspid regurgitation. Severe or massive tricuspid regurgitation was present in 88% of patients, and 22 patients were also treated with the MitraClip system for mitral regurgitation in a combined procedure. The MitraClip device was successfully implanted in the tricuspid valve in 97% of cases. After the procedure, tricuspid regurgitation was reduced by at least one grade in 91% of the patients. In 13% of patients, tricuspid regurgitation remained severe after the procedure. No intraprocedural deaths, cardiac tamponade, emergency surgery, stroke, myocardial infarction, or major vascular complications occurred. Three (5%) in-hospital deaths occurred. NYHA class was significantly improved ($p<0.001$), and 6MWD increased significantly (165.9±102.5 minutes versus 193.5±115.9 minutes; $p=0.007$).

Section Summary

There is not enough research to show that percutaneous transcatheter tricuspid valve repair improves health outcomes for people with tricuspid regurgitation. Available evidence includes

one randomized controlled trial with one year follow-up time. Additional controlled studies with longer follow-up times are needed.

TRANSCATHETER TRICUSPID VALVE ANNULUS RECONSTRUCTION

Nonrandomized Studies

Zhang (2023) published a compassionate use study of the K-clip transcatheter annular repair system for severe functional TR.[33] 15 patients were enrolled. At 30 days, reductions in tricuspid annular circumference (by 14.30%) and area (by 25.96%) were observed. No major adverse events were reported at 30 days. Clinical evaluation indicated that 86.67% of patients were finally in NYHA functional class I or II ($p<0.001$), and overall KCCQ score improved from 62.28 ± 18.97 to 77.90 ± 11.70 ($p=0.016$). This study is limited by small sample size and lack of a comparison group. The authors concluded that while early results are promising, controlled trials with longer term follow-up are necessary to establish the safety and effectiveness of transcatheter valve annulus reconstruction devices.

Gray (2022) published one-year outcomes from a single-arm multi-center study of tricuspid regurgitation treated via annual reduction with the Cardioband Tricuspid Valve Reconstruction System.[34] 37 patients with functional (97.3%) or mixed (2.7%) tricuspid regurgitation were enrolled. One-year follow-up was available for 29 patients. Tricuspid annular diameter significantly decreased ($p<0.0001$). Echocardiogram demonstrated significant reductions in tricuspid regurgitation severity between 30 days and six months ($p=0.0029$) and at one year ($p<0.0001$). NYHA functional class improved at one year ($p<0.0001$). At one year cardiovascular mortality was 8.1% (n=3) with one death deemed possibly related to the study device. The severe bleed rate was 35.1%. The study was limited by small sample size, and lack of control arm.

Davidson (2021) published 30 day outcomes from an early feasibility study of the Cardioband tricuspid system for the treatment of functional tricuspid regurgitation.[35] 30 patients with severe or greater symptomatic functional tricuspid regurgitation were enrolled who were deemed candidates for transcatheter tricuspid repair with the Cardioband tricuspid system by the local heart team and multidisciplinary screening committee. The mean patient age was 77 years. 80% of patients were women, 97% had atrial fibrillation, 70% were in NYHA functional class III to IV with mean left ventricular ejection fraction of 58%, and 27% had severe, 20% massive, and 53% torrential tricuspid regurgitation. Device success was 93% and all patients were alive at 30 days. Between baseline and 30 days, septolateral tricuspid annular diameter was reduced by 13% ($p<0.001$), 85% of patients had greater than or equal to one grade tricuspid regurgitation reduction. 44% of patients had moderate or less tricuspid regurgitation, 75% were in NYHA functional class I to II ($p<0.001$), and overall Kansas City Cardiomyopathy Questionnaire (KCCQ) score improved by 16 points ($p<0.001$).

Nickenig (2021) reported a prospective single-arm study of 30 patients implanted with the Cardioband tricuspid valve reconstruction system for the treatment of moderate or severe functional tricuspid regurgitation (TRI-REPAIR study).[36] Outcomes were collected prospectively for up to two years, with a mean duration of 604 days. Technical success was 100%. Prior to implantation, 83% of patients were in NYHA Class III to IV, and at two years 82% of patients were in NYHA Class II to II ($p=0.02$). 6MWD and KCCQ scores improved by 73 minutes ($p=0.058$) and 14 points ($p=0.046$), respectively. There were eight deaths within the two-year follow-up. This study is limited by lack of a comparison group and small sample size.

Section summary

There is not enough research to show that transcatheter tricuspid valve annulus reconstruction improves health outcomes for people with tricuspid valve regurgitation. While early results of studies investigating tricuspid valve annulus reconstruction are promising, controlled trials are necessary to establish the safety and effectiveness of transcatheter valve annulus reconstruction devices.

TRANSCATHETER TRICUSPID VALVE REPLACEMENT

Nonrandomized Studies

Kodali (2023) conducted a prospective, single-arm study in 176 participants and reported major adverse events, reduction in regurgitation grade and hemodynamic outcomes by echocardiography, and clinical, functional, and quality-of-life parameters.[37] Patients were 71.0% female, mean age 78.7 years, 88.0% with greater than or equal to severe tricuspid regurgitation, and 75.4% New York Heart Association classes III-IV. Tricuspid regurgitation was reduced to less than or equal to mild in 97.6% ($p<0.001$), with increases in stroke volume (10.5 ± 16.8 mL, $p<0.001$) and cardiac output (0.6 ± 1.2 L/min, $p<0.001$). 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 ($p<0.001$), and six-minute walk distance increased by 56.2 m ($p<0.001$). All-cause mortality was 9.1%, and 10.2% of patients were hospitalized for heart failure. Longer-term follow-up is needed to confirm sustained improvements in these outcomes.

Section Summary

There is not enough research to show that transcatheter tricuspid valve replacement improves health outcomes for people with tricuspid regurgitation. Additional studies using comparative designs with adequate follow-up are needed.

CAVAL VALVE IMPLANTATION (CAVI)

Nonrandomized studies

Estevez-Loureiro (2022) published six-month outcomes from the Safety and Efficacy of the TricValve® Transcatheter Bicaval Valves System (TRICUS EURO) study, a prospective single-arm study with 35 patients from 12 institutions in Spain and Austria.[38] The study participants had NYHA functional class III or IV TR, symptoms of right heart failure, and were ineligible for open heart surgery. The primary endpoint was NYHA functional class and quality of life (QOL) measured with the Kansas City Cardiomyopathy Questionnaire (KCCQ) at six-months after valve implantation. Secondary endpoints included major adverse events and functional capacity measured with a six-minute walk test. Compared to baseline, there was significant improvement in NYHA functional class at six months with 79.4% of participants in functional class I or II ($p=0.0006$). KCCQ scores were also significantly improved at six months ($p=0.004$). There were three deaths at six months, but none were procedural or recorded as cardiovascular. Major bleeding was seen in six participants (17.1%), all of whom were receiving anticoagulation. Two cases of bleeding were due to access-site complications. Seven participants (20%) were readmitted to the hospital for heart failure. The difference in six-minute walk test distance was not significant ($p=0.46$). The authors concluded that CAVI led to improved functional status and QOL with a low rate of procedural complications, but longer term follow-up is needed.

Blasco-Turrion (2024) published one-year follow-up data from the TRICUS EURO study, with additional information from the TRICUS study, an early feasibility study with nine participants (n=44).[39] At one year, 42 participants (95.5%) had at least one of the following: an increase of ≥15 points in KCCQ score, improvement to NYHA functional class I or II, or an increase of ≥40 meters in the six-minute walk test. There were three deaths (6.8%) at one year and 29.5% of participants were hospitalized for heart failure. Hepatic vein backflow was alleviated in 63.8% of patients leading to reduced congestive heart symptoms, n-terminal pro-B-type natriuretic peptide levels, and diuretic treatment. The authors concluded that CAVI treatment using TricValve® system is safe and leads to stable functional and QOL improvement.

Section Summary

There is not enough research to show that caval valve implantation improves health outcomes for people with tricuspid regurgitation. CAVI devices are potentially promising alternatives in the treatment of tricuspid valve regurgitation, however there is a need for additional research on CAVI devices using comparative designs with follow-up assessment.

PRACTICE GUIDELINE SUMMARY

American Heart Association (AHA) and American College of Cardiology (ACC)

In 2020, the American College of Cardiology and American Heart Association released joint clinical practice guidelines for the management of valvular heart disease.[1] The guidelines do not address the procedures in this policy.

SUMMARY

TRANSCATHETER MITRAL VALVE REPAIR

There is enough research to show that transcatheter mitral valve replacement (TMVR) can improve health outcomes for people with previously placed, failed bioprosthetic mitral valves. Compared to surgery, TMVR is associated with fewer procedure-related complications (e.g., stroke, bleeding), possibly a lower rate of in-hospital mortality, with no difference in post-procedure outcomes at 30 days and one-year. Therefore, TMVR may be considered medically necessary for people who meet policy criteria.

There is not enough evidence to show that transcatheter mitral valve replacement (TMVR) improves health outcomes for mitral valve regurgitation due to native mitral valve disease. Therefore, TMVR is considered investigational when policy criteria are not met.

TRANSAPICAL MITRAL VALVE REPAIR WITH PLACEMENT OF ARTIFICIAL CHORDAE TENDINAE

There is not enough research to show that transapical mitral valve repair with placement of artificial chordae tendinae improves health outcomes of people with mitral valve regurgitation. The current evidence is limited by retrospective study designs and small sample sizes. Prospective studies that compare transapical mitral valve repair with placement of artificial chordae tendinae to other treatments are needed. Therefore,

transapical mitral valve repair with placement of artificial chordae tendinae is considered investigational for people with mitral valve regurgitation.

TRANSCATHETER MITRAL VALVE ANNULOPLASTY RECONSTRUCTION (TMVAR)

There is not enough research to show that transcatheter mitral valve annuloplasty reconstruction (TMVAR) improves health outcomes for people with mitral valve regurgitation. Therefore, TMVAR is considered investigational for people with mitral valve regurgitation.

PERCUTANEOUS TRANSCATHETER TRICUSPID VALVE REPAIR

There is not enough research to show that percutaneous transcatheter tricuspid valve repair improves health outcomes for people with tricuspid regurgitation. Therefore, percutaneous transcatheter tricuspid valve repair is considered investigational for people with tricuspid regurgitation.

TRANSCATHETER TRICUSPID VALVE ANNULUS RECONSTRUCTION

There is not enough research to show that transcatheter tricuspid valve annulus reconstruction improves health outcomes for people with tricuspid valve regurgitation. Therefore, transcatheter tricuspid valve annulus reconstruction is considered investigational.

TRANSCATHETER TRICUSPID VALVE REPLACEMENT

There is not enough research to show that transcatheter tricuspid valve replacement improves health outcomes for people with tricuspid regurgitation. Therefore, transcatheter tricuspid valve replacement is considered investigational for people with tricuspid regurgitation.

CAVAL VALVE IMPLANTATION

There is not enough research to show that caval valve implantation improves health outcomes for people with tricuspid regurgitation. Therefore, caval valve implantation is considered investigational for people with tricuspid regurgitation.

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CODES

Codes	Number	Description
CPT	0483T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed
	0484T	Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)
	0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae
	0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
	0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
	0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis
	0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to the primary procedure)
	0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
	0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
	0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
HCPCS	None	

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