Molina Clinical Policy
Transcatheter Tricuspid Valve Repair or Replacement
Policy No. 368

Last Approval: 08/13/2025
Next Review Due By: August 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Tricuspid valve (TV) disease is a condition in which the valve between the two right heart chambers (right ventricle and right atrium) does not function properly. TV disease often occurs with other heart valve problems. Tricuspid regurgitation (TR) is a commonly encountered manifestation of valvular heart disease. Many patients with TR have mild disease, classified as nonpathological or a normal variant. These patients can remain asymptomatic for some time. Moderate-to-severe TR is usually considered pathological and is associated with poor prognosis. The incidence of TR in the United States ranges from 5% to 20% in adults and is most common in individuals older than 65 years. If left untreated, TV disorders that occur with cardiopulmonary disease can increase morbidity and mortality.

TV surgery is rarely performed on an isolated basis and is usually performed at the same time as surgery for left-sided heart disease. Indications depend on whether surgery for mitral or aortic valve disease is indicated. For patients with severe TR who are undergoing left-sided valve surgery, TV surgery is recommended. For isolated TV surgery, optimum timing is not well established. Between 2004 and 2013, there were 5005 isolated TV surgeries performed in the United States, with an operative mortality of 8.8%. TV repair or replacement is performed to control regurgitation and improve or prevent symptoms, and TV repair is generally preferred to replacement. While observational data suggests that TV surgery can improve functional capacity, little evidence exists on the impact of survival. TV surgery is associated with high risk of atrioventricular block requiring permanent pacemaker implantation. For patients with contraindications to open surgery, repair or replacement by a transcatheter approach may be an attractive option (Hayes 2024; Otto 2025).

Transcatheter tricuspid valve interventions, which include replacement or repair, are minimally invasive procedures involving the insertion of an artificial heart valve or repair device using a catheter, rather than through open-heart surgery. For valve replacement, an expandable prosthetic heart valve is pressed onto a catheter and then deployed at the site of the diseased native valve. For valve repair, a small device is deployed by catheter to the valve where the faulty leaflets are clipped together to reduce regurgitation (Hayes 2024; Otto 2025). Some evidence suggests transcatheter interventions have advantages in perioperative outcomes, lower in-hospital mortality, lower pacemaker implantation rates, but more frequent valve reintervention rates. Evidence suggests comparable mortality rates between open TV surgery and transcatheter interventions (Shimoda et al. 2024).

Regulatory Status

Transcatheter tricuspid valve devices are regulated by the FDA as Class III medical devices and generally defined as percutaneously delivered valve prostheses or repair devices and are approved through the premarket approval process under product code NPW and NPS, respectively. In 2024, the FDA approved the TriClip G4 System (Abbott Medical), indicated for transcatheter edge-to-edge valve repair in patients with severe tricuspid regurgitation. It is the only FDA approved device for transcatheter tricuspid repair, but there are several other devices in active interventional trials, including the Pascal System (Edwards Lifesciences), Cardioband (Edwards Lifesciences), and TriCinch (4Tech Cardio). In 2024, the FDA approved the Evoque Tricuspid Valve Replacement System (Edwards Lifesciences), indicated for transcatheter tricuspid valve replacement in patients with severe tricuspid regurgitation. It is the only FDA approved device for this indication, but there are several other devices in active interventional trials, including the Lux-Valve (Jenscare Scientific), Cardiovalve (Cardiovalve), VDYNE (VDYNE), Intrepid (Medtronic), and TriSol (TriSol Medical).

COVERAGE POLICY

Transcatheter tricuspid valve replacement or repair is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Transcatheter Tricuspid Valve Repair

Randomized Controlled Trials

Sorajja et al. (2023) reported on a prospective randomized open label TRILUMINATE pivotal trial of tricuspid transcatheter edge-to-edge repair (TEER) for severe TR. At total of 350 patients were enrolled and assigned in a 1:1 ratio to either receive TEER (n=175) or medical therapy (n=175). The end point composite included death from any cause or tricuspid-valve surgery; hospitalization for heart failure; and an improvement in quality of life. The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to assess improvement determined by a minimum of at least a 15-point increase from the initial score (higher score indicating a better quality of life) at one-year follow-up. Patients mean age was 78 years and 54.9% were women. Both the study and control groups did not differ regarding the incidence of death, tricuspid-valve surgery, or hospitalization for heart failure. The most significant difference between the two groups was KCCQ quality-of-life scores. The study patients in the TEER group improved the mean (±SD) of 12.3±1.8 points in the TEER group, as compared with 0.6±1.8 points in the control group (P<0.001). At 30-days post procedure 87% of the TEER group had TR that was moderate or less when compared to 4.8% of the control group. The safety of the TEER group overall reported 98.3% free from adverse events, concluding that the procedure benefited patients with severe TR disease. (ClinicalTrials.gov ID: NCT03904147).

Arnold et al. (2024) reported on the 1 year follow up data of the prospective randomized open label TRILUMINATE pivotal trial evaluating tricuspid TEER to reduce TR compared to medical therapy alone. Patients with severe TR were randomized to T-TEER (n=175) or conventional medical management (n=175). Health status was assessed at baseline, 1, 6, and 12 months utilizing the KCCQ and defined “alive and well” as a KCCQ overall score of > 60 and no decline from baseline of > 10 points at one year. When overall health status was analyzed TEER significantly improved health status at 1 month (mean between-group difference in KCCQ overall summary score 9.4 points; 95% CI: 5.3-13.4 points), with a small additional improvement at 1 year (mean between-group difference 10.4 points; 95% CI: 6.3-14.6 points). TEER patients were more likely to be alive and well at 1 year (TEER vs medical therapy: 74.8% vs 45.9%; P < 0.001). Further analysis of the health status benefit suggests that TR symptom reduction and quality of life improvement, paired with reduced 1 year mortality and heart failure hospitalization were the main contributors to TEER’s health status improvement scores. (ClinicalTrials.gov ID: NCT03904147).

Kar et al. (2025) reported on the two-year outcomes of the TRILUMINATE Pivotal Trial, a RCT to evaluate the safety and efficacy of TEER using the TriClip device in patients with severe symptomatic TR. A total of 572 patients were randomized 1:1 to receive either TEER plus medical therapy (device group) or medical therapy alone (control group). Patients were followed for two years, and prespecified secondary endpoints included rate of recurrent heart failure hospitalization and freedom from all-cause mortality, tricuspid valve surgery, or other tricuspid interventions. At two years, the annualized rate of recurrent heart failure hospitalization was significantly lower in the TEER group compared to the control (0.19 vs. 0.26 events per patient-year, p = 0.02), corresponding to a 28% relative risk reduction. Freedom from all-cause mortality, surgery, or intervention was significantly higher in the TEER group (77.6% vs. 29.3%, p < 0.0001), largely due to a high rate of crossover in the control group (61.5% underwent TEER after the 1-year mark). Despite this, all-cause mortality (17.9% vs. 17.1%) and tricuspid valve surgery rates (2.3% vs. 4.3%) were similar between groups at two years. TEER led to sustained reductions in TR severity, with 84% of device-treated patients

having moderate or less TR at two years. Health status, measured by the KCCQ, improved by an overage of 15.4 points in the device group. For adverse events in the TEER group, stroke occurred in 1.9% of patients, TIA in 1.7%, permanent pacemaker placement in 7.4%, and major bleeding in 2.8%. There were no cases of device embolization or thrombosis. As the trial allowed crossover from the control group to TEER after one year, of the 241 eligible, 59% crossed over. Following crossover, TR severity was reduced to moderate or less in 81% of patients, KCCQ score improved by 12.8 points, and heart failure hospitalization rate dropped from 0.50 to 0.35 events per patient-year post procedure. The remaining patients who did not crossover generally had better baseline status and exhibited modest improvements in quality of life and some TR reduction, with a KCCQ gain of 10.3 points and a heart failure hospitalization rate increase from 0.08 to 0.28 events per patient year. The authors concluded that tricuspid TEER was safe, reduced TR severity, improved quality of life, and decreased heart failure hospitalization at two years. TEER was also effective and safe when administered after a one-year delay, although patients experienced more symptom burden and heart failure hospitalization before receiving the device. The authors acknowledged study limitations such as a high crossover rate resulting in small size of the pure control group, and differences in symptom severity that may affect group comparisons.

Systematic Reviews and Meta-Analyses

Saito et al. (2025) conducted a systematic review and meta-analysis to compare four treatment strategies for isolated TR: medical therapy alone, transcatheter tricuspid valve (TV) repair, surgical TV repair, and surgical TV replacement. The review included 22 studies, with 1 RCT and 21 observational studies, for a total of 25,831 patients. The studies spanned a mean follow-up of approximately 42 months. The primary outcome was long-term mortality (≥ 1 year), and secondary outcomes included short-term mortality (in hospital or 30-day), length of hospital stay, and periprocedural complications (e.g., bleeding, new pacemaker implantation, renal complications, and cardiogenic shock). The meta-analysis found that medical therapy alone was associated with significantly higher long-term mortality when compared to all other interventions: surgical TV repair (hazard ratio [HR] 1.72, 95% CI 1.34-2.23), surgical TV replacement (HR 1.49, 95% CI 1.14-1.96), and transcatheter TV repair (HR 1.52, 95% CI 1.30-1.78). Long term mortality was similar between transcatheter and surgical TV repair. Transcatheter TV repair was associated with better short-term outcomes, as it demonstrated lower short-term mortality compared to surgical TV repair (risk ratio [RR] 0.40, 95% CI 0.22-0.72) and surgical TV replacement (RR 0.35, 95% CI 0.19-0.66), and fewer periprocedural complications. Hospital stays were also shorter with transcatheter approaches. Most patients who underwent transcatheter TV repair had secondary TR, while those undergoing surgical treatment more often had primary TR. Transcatheter repairs primarily utilized edge-to edge coaptation techniques, with some variability between devices. The authors noted a concern for risk of bias due to the dominance of observational studies in the review, and due to selection bias, as patients receiving medical therapy may not have been candidates for surgery or transcatheter procedures. The authors concluded that medical therapy alone results in higher long-term mortality, and that TV repair offers favorable short-term safety and comparable long-term survival to surgical repair. Given its minimally invasive nature and lower complication rates, transcatheter TV repair appears to be an attractive option for selected patients with TR, although further research is needed to refine patient selection and evaluate long-term outcomes.

Patel et al. (2025) conducted a systematic review and meta-analysis comparing transcatheter tricuspid valve interventions (TTVI), including both repair and replacement, to both surgical and guideline-directed medical therapy (GDMT) for TR. The review included 11 reports from 10 observational studies, for a total of 5798 participants for the surgical comparison (2243 TTVI, 3555 surgical), while sample sizes for the medical therapy comparison ranged from 53 to 1200 per group across five studies. The meta-analysis found that TTVI was associated with significantly lower 30-day mortality (OR 0.32, 95% CI: 0.20-0.50, $p < 0.00001$), shorter hospital stays (mean difference -7.33 days, 95% CI: -8.23 to -6.42, $p < 0.0001$), and fewer complications, such as acute kidney injury (OR 0.56 $p < 0.00001$), respiratory complications (OR 0.45, $p = 0.00001$), and atrioventricular block (OR 0.09, $p = 0.007$) when compared to surgery. The need for permanent pacemaker implantation was also lower in the TTVI group (OR 0.12, $p = 0.01$). When compared to GDMT, TTVI consistently reduced mortality and hospitalizations for heart failure. For example, one study showed a one-year mortality of 23% in the TTVI group vs. 36% in the GDMT group ($p = 0.001$), while another study showed a two-year survival of 93% with TTVI vs. 79% with GDMT in patients with a low TRI-SCORE ($p = 0.0002$). The authors noted several limitations of the review, including the observational nature of the included studies, selection bias, short term follow-up, and lack of control for confounders. Additionally, patients in TTVI studies tended to be older and more comorbid than those undergoing surgery, which could influence outcomes. The authors emphasized the need for more RCTs and long-term data to study safety and effectiveness. The authors concluded that TTVI appears to be effective in older, high-risk patients who are considered unsuitable for surgery, and that observational data suggests TTVI is superior to medical therapy alone. However, these findings are based on limited and mostly non-randomized evidence.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Kodali et al. (2023) study reported one-year outcomes with the PASCAL (Edwards Lifesciences) transcatheter valve edge-to-edge repair system, including safety and performance. This trial (n = 65) was a single arm, multicenter, prospective study with clinical, functional, and echocardiographic analysis. TR severity was significantly reduced with 31 of 36 (86.0%) of patients reporting a reduction of symptoms achieving moderate or less based on New York Heart Association functional class. In addition, six-minute walking distance increased by 94 m (P =0.014), and overall KCCQ scores increased by 18 points (P < 0.001). The PASCAL system correlates with low complication and high survival rates with improved functional status and quality of life at one-year post-procedure. (ClinicalTrials.gov NCT03745313).

Lurz et al. (2021) reported one-year outcomes with the TriClip (Abbott Vascular) transcatheter tricuspid valve system including repair durability, clinical benefit and safety in a patient population that was fragile and at high surgical risk. This trial (n = 85) was an international, prospective, single arm, multicenter study. The TriClip device reduced TR to moderate or less in 71% of subjects when compared with 8% at baseline. Clinical improvements were assessed utilizing New York Heart Association (NYHA) functional class I/II (31% to 83%, p < 0.0001), six-minute walk test (272.3 ± 15.6 to 303.2 ± 15.6 meters, p = 0.0023) and KCCQ score (improvement of 20 ± 2.60 points, p < 0.0001). It is noted that patients demonstrated reverse right ventricular remodeling in terms of size and function. At one-year, all-cause mortality and major adverse event were both 7.1%. The TriClip device proved to be durable and correlated with significant clinical improvement and low mortality in patients with moderate or greater TR. (ClinicalTrials.gov NCT03227757).

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 TR in 30 patients enrolled in the TRI-REPAIR (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 6 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% were female, and 23% had ischemic heart disease. At baseline, 83% were in NYHA functional class III to IV and mean left ventricular ejection fraction was 58%. Technical success was 100%. Through 6 months, 3 patients died. Between 6 months and baseline, echocardiography showed average reductions of annular septolateral diameter of 9% (42 mm vs. 38 mm; p <0.01), proximal isovelocity surface area effective regurgitant orifice area of 50% (0.8 cm2 vs. 0.4 cm2; p <0.01), and mean vena contracta width of 28% (1.2 cm vs. 0.9 cm; p <0.01). Clinical assessment showed that 76% of patients improved by at least 1 NYHA functional class with 88% in NYHA functional class I or II. Six-minute walk distance improved by 60 m (p <0.01), and KCCQ score improved by 24 points (p <0.01). In conclusion, six-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. (ClinicalTrials.gov NCT0298195).

Transcatheter Tricuspid Valve Replacement

Randomized Controlled Trials

Hahn et al. (2025) reported on the TRISCEND II trial, a multinational, prospective randomized controlled trial (RCT) evaluating the safety and effectiveness of transcatheter tricuspid valve replacement using the EVOQUE system compared to medical therapy alone in patients with severe symptomatic tricuspid regurgitation (TR). A total of 400 patients were enrolled and randomized in a 2:1 ration, with 267 patients assigned to the valve-replacement group and 133 to the control group. Patients were followed for one year, with the primary endpoint being a hierarchical composite of all-cause mortality, repeat tricuspid intervention, heart failure hospitalization rate, improvements in quality of life and functional status, and the need for right ventricular assist device or heart transplantation. Quality of life was measured using the Kansas City Cardiomyopathy Questionnaire overall summary score (KCCQ-OS), with a ≥ 10-point improvement considered clinically significant. Functional status was assessed using the New York Heart Association (NYHA) classification and 6-minute walk distance, with ≥ 30 meters increase considered meaningful. At one year, the trial found that transcatheter valve replacement significantly outperformed medical therapy alone on the composite primary outcome with a ratio of 2.02 (95% CI, 1.56 to 2.62; p < 0.001). Patients in the valve replacement group also showed greater improvements in KCCQ-OS (mean increase of 18.4 points vs. 6.0%), NYHA class (78.9% had at least a one-class improvement vs. 24.0%), and 6-minute walk distance. Tricuspid regurgitation was reduced to mild or less

in 95.2% of patients in the valve replacement group compared to 2.3% in the control group. Right ventricular remodeling also improvement in the replacement group as evidenced by reductions in end-diastolic dimension and vena cava diameter. Adverse events were more frequent in the replacement group, with severe bleeding occurring in 15.4% of patients versus 5.3% in controls (p = 0.003), and new permanent pacemaker implantation was required in 17.8% vs. 2.3% respectively (p < 0.001). The overall rate of death from any cause was numerically lower in the replacement group (12.6% vs. 15.2%), as were hospitalizations for heart failure (20.9% vs. 26.1%), although the trial was not powered to detect statistical significance for these individual outcomes. Potential bias included differential dropout and crossover rates, and a high rate of atrial fibrillation (94.9%) with atrial rather than ventricular secondary tricuspid regurgitation, which may have a more favorable prognosis. The authors concluded that transcatheter tricuspid valve replacement with medical therapy was superior to medical therapy alone in patient with severe symptomatic tricuspid regurgitation due to improvements in symptoms, functional capacity, and quality of life. Procedural risks such as bleeding and the need for permanent pacing must be carefully weighed during shared decision making. (ClinicalTrials.gov NCT04482062).

Systematic Reviews and Meta-Analyses

Azami et al. (2025) conducted a systematic review and meta-analysis to evaluate the efficacy and safety of transcatheter TV replacement (TTVR) in patients with moderate to severe TR. The review included 21 studies, including 13 observational studies and 4 case series, for a total of 643 patients. The pooled technical success rate of TTVR was 94%, in-hospital mortality rate was 8%, 30-day mortality was 4%, 6-month mortality was 6%, and 1-year mortality was 9%. The meta-analysis showed significant improvement in echocardiographic indices, notably a reduction in TR severity (OR = 0.0013, p < 0.001), a mean reduction in pulmonary artery systolic pressure of -8.69 mmHg, and a reduction in right ventricle end-diastolic mid diameter by -6.33 mm. However, no significant changes were observed in left ventricular ejection fraction, TV mean gradient, right ventricular fractional area change, or tricuspid annular plane systolic excursion, suggesting that some aspects of right heart function may not improve post-procedure. From a clinical standpoint, TTVR led to significant improvements, including a decrease in New York Heart Association function class III/IV status (OR 0.03), edema (OR 0.09), and ascites (OR = 0.11). Additionally, quality of life, as assessed by the Kansas City Cardiomyopathy Questionnaire improved by 25 points, and functional capacity measured by the 6-minute walk test increased by 82.24 meters. The most common adverse events were bleeding (10%), pulmonary complications (10%), and valve thrombosis. Acute kidney injury occurred in 2% of patients, and device migration, non-elective reintervention, and conversion to surgery were approximately 1%. The authors concluded that TTVR is a promising and safe alternative for high-risk patients with severe TR. However, RCTs, standardized endpoints, and long-term follow-up studies are needed.

Bugan et al. (2022) conducted a systematic review and meta-analysis analyzing the feasibility of transcatheter tricuspid valve replacement. Nine studies were included in the analysis, totaling 321 patients. Severe TR was diagnosed in 95% of patients (95% CI: 89% to 98%), and 83% (95% CI: 73% to 90%) of patients were in NYHA functional class III or IV. At a weighted mean follow-up of 122 days post – procedure revealed the prevalence of severe TR significantly reduced, the NYHA functional class significantly improved (risk ratio = 0.20; 95% CI: 0.11 to 0.35; P <.001), as well as the 6-minute walking distance (mean difference = 91.1 m; 95% CI: 37.3 to 144.9 m; P <.001). A total of 28 patients died; however, pooled analyses did not detect statistically significant differences in the in hospital, 30-day mortality, and >30-day mortality compared to predicted operative mortality (risk ratio = 1.03; 95% CI: 0.41 to 2.59; P =.95, risk ratio = 1.39; 95% CI: 0.69 to 2.81; P =.35, respectively). The authors concluded that transcatheter tricuspid valve replacement is a viable emerging procedure in treating non-surgical candidates with severe TR.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Kodali et al. (2023) analyzed the one-year outcomes of the TRISCEND prospective single arm clinical study on transfemoral tricuspid valve replacement. One hundred and seventy-six patients were enrolled, with the primary outcomes of safety and efficacy in treating > moderate symptomatic TR. Of the 176 patients, 88% had severe TR and 75.4% had a NYHA functional class III or IV. The one year follow up results revealed TR was reduced to ≤mild in 97.6% of patients (P < .001), with a corresponding 93.3% achieving a NYHA functional class I or II (P < .001). The overall KCCQ score increased by 25.7 points (P < .001), and six-minute walk distance increased by 56.2 m (P < .001). At one year 10.2% of patients had been hospitalized for heart failure, and all-cause mortality was 9.1 percent. The authors concluded that the EVOQUE transcatheter tricuspid valve replacement system sustained significant TR reduction the highly comorbid elderly population. (ClinicalTrials.gov NCT04221490).

National and Specialty Organizations

The **American Heart Association (AHA)** and the **American College of Cardiology (ACC)** published the *Guideline for the Management of Patients with Valvular Heart Disease.* Recommendations for the evaluation and management of valvular heart disease continue to be based on clinical experience and observational studies, with prospective RCTs limited mostly to new devices. The guideline recommends that research on valve disease spans the spectrum from basic science to prospective randomized trials. Research should include medical therapy, and studies should focus on each stage of the disease process (e.g., from the patient at risk to the patient with end-stage disease). Most cases of significant TR are secondary and related to tricuspid annular dilation and leaflet tethering in right ventricle remodeling. In addition, some patients may have significant isolated TR due primarily to annular dilation, often associated with atrial fibrillation in the absence of pulmonary hypertension or left ventricle systolic dysfunction. The severity of TR can be dynamic and dependent on changes in preload and pulmonary pressure, with symptoms such as fatigue, abdominal bloating, and peripheral edema (Otto et al. 2021).

For patients with right-sided heart failure attributable to severe TR (Stage C or D), the guidelines recommend diuretics and other supportive care, such as a low-salt diet and support stockings. For patients with right-sided heart failure attributable to severe secondary TR (Stage C or D), the guidelines recommend therapies to treat the primary cause of heart failure, such as pulmonary vasodilators, guidelines directed medical therapy, or rhythm control. Patients with severe symptomatic isolated tricuspid regurgitation may benefit from surgical intervention to reduce symptoms and recurrent hospitalizations if done before the onset of severe right ventricular dysfunction or end-organ damage to the liver and kidney. Surgical treatment is performed for select patients with TR at the time of surgery for left-sided valve disease to prevent progression of TR. Intervention for severe isolated TR has a high reported operative mortality rate, ranging from 8% to 20%. While operative mortality rate may be attributable to end-organ damage, outcomes in general for severe primary TR are poor with medical management. Correction of symptomatic severe primary TR (Stage D) without left-sided valve disease would ideally be performed before the onset of significant right ventricular dysfunction or end-organ damage; however, randomized studies of early intervention are lacking, and the benefit may be limited by the risk of intervention and suboptimal reduction in TR severity (Otto et al. 2021).

The **European Society of Cardiology (ESC)** and **European Association for Cardiothoracic Surgery (EACTS)** published guidelines on the management of valvular heart disease. The guidelines note that atrial fibrillation induces annular remodeling even in the absence of left-sided heart disease. Cardiac implantable electronic device-lead implantations lead to progressive tricuspid regurgitation in 20-30% of the patients and predicts its progression over time. In patients with heart failure and reduced left ventricular ejection fraction, secondary TR is a very frequent finding and is an independent predictor of clinical outcomes. Surgery is recommended in symptomatic patients with severe primary TR, but the benefit of surgical correction of isolated secondary tricuspid regurgitation compared to medical treatment is not well established, and the procedure has a non-negligible risk of peri-procedural mortality and morbidity when patients present late. Transcatheter tricuspid valve interventions are under clinical development, and early data has demonstrated the feasibility to reduce TR with subsequent symptomatic and hemodynamic improvement. Transcatheter tricuspid valve interventions may be considered by the heart team at experienced centers in symptomatic, inoperable, anatomically eligible patients in whom symptomatic or prognostic improvement can be expected (Vahanian et al. 2021).

The **National Institute for Health and Care Excellence (NICE)** (2022) issued an interventional procedure guidance [IPG731] on *Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation* (TTVR), stating that evidence on TTVR efficacy is limited in quality and quantity, and studies on its safety show serious, but well-recognized complications. NICE recommends that for those with severe and symptomatic tricuspid regurgitation, TTVI should only be performed with special arrangements for clinical governance, consent, audit, or research and performed at specialized centers with experience of the interventional management of tricuspid regurgitation. For those with mild to moderate tricuspid regurgitation, TTVI should only be performed in the setting of research, as evidence on the safety and efficacy is inadequate in quality and quantity for this population.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus

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 code for primary procedure)
0646T	Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
33999	Unlisted procedure cardiac surgery [when specified as transcatheter tricuspid valve replacement or repair]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

08/13/2025	Policy reviewed. No change to coverage criteria.
08/14/2024	Policy reviewed. No change to coverage criteria.
08/09/2023	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections. Removed Supplemental information section. IRO Peer Review July 17, 2023, by a practicing, board-certified physician in Cardiovascular Disease.
08/10/2022	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and Reference sections.
08/13/2021	Policy reviewed, no changes, updated references.
06/17/2020	New policy. IRO Peer Review completed April 19, 2020.

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