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

Last Approval: 08/14/2024
Next Review Due By: August 2025

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 disease is a condition in which the valve between the two right heart chambers (right ventricle and right atrium) does not function properly. Tricuspid valve 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 that is 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 prevalence of moderate-to-severe TR in the United States has been reported to be greater than 1.6 million. With severe TR, one-year mortality increases and may reach greater than 36%. Surgical repair of TR is generally reserved for patients with advanced disease. These patients are often high-risk candidates for open surgical procedures, making the percutaneous or transcatheter minimally invasive approach attractive for this population. The current standard of care is open surgical valve replacement or repair surgery (Otto 2023; Hayes 2023).

Transcatheter tricuspid valve interventions (TTVI), which include replacement or repair of the tricuspid valve, are minimally invasive procedures involving the insertion of an artificial heart valve or repair device using a catheter, rather than through open heart surgery, or surgical valve replacement. For valve replacement surgery, 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. Advantages of percutaneous transcatheter heart valve surgery procedure are it usually takes less time to perform and is less traumatic than open heart surgery. Potential disadvantages of transcatheter heart valve surgery include a greater risk for valve migration, complications associated with catheter-based delivery, and uncertain valve device durability (Otto 2023; Hayes 2023).

Regulatory Status

The Food and Drug Administration (FDA) approved the TriClip G4 System (Abbott Medical) in April 2024 under the product code NPS in the Premarket Approval Database. The device is indicated for transcatheter edge-to-edge valve repair in patients with severe tricuspid regurgitation and is the only FDA approved device for transcatheter tricuspid repair. There are several other devices in active interventional trials intended for tricuspid valve repair, including the Pascal System (Edwards Lifesciences), Cardioband (Edwards Lifesciences), and TriCinch (4Tech Cardio).

The FDA approved the Evoque Tricuspid Valve Replacement System (Edwards Lifesciences) in February 2024 under the product code NPW in the Premarket Approval Database. The device is indicated for transcatheter tricuspid valve replacement in patients with severe tricuspid regurgitation and is the only FDA approved device for this indication. There are several other devices in active interventional trials intended for tricuspid valve replacement, including the Lux-Valve (Jenscare Scientific), Cardiovalve (Cardiovalve), VDYNE (VDYNE), Intrepid (Medtronic), and TriSol (TriSol Medical).

COVERAGE POLICY

Transcatheter tricuspid valve replacement or repair are considered **experimental, investigational, or unproven** due to insufficient published evidence to assess the safety and/or impact on health outcomes in patients with diseased tricuspid valves.

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

Arnold et al. (2024) reported on the 1 year follow up data of the prospective randomized open label TRILUMINATE pivotal trial evaluating tricuspid transcatheter edge to edge repair (T-TEER) to reduce tricuspid regurgitation (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 Kansas City Cardiomyopathy Questionnaire (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 T-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). T-TEER patients were more likely to be alive and well at 1 year (T-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 T-TEER’s health status improvement scores (Identifier: NCT03904147).

Sorajja et al. (2023) reported on a prospective randomized trial of T- TEER for severe TR. At total of 350 patients were enrolled and assigned in a 1:1 ratio to either receive T-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 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 T-TEER group improved the mean (±SD) of 12.3±1.8 points in the T-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 T-TEER group had TR that was moderate or less when compared to 4.8% of the control group. The safety of the T-TEER group overall reported 98.3% free from adverse events, concluding that the procedure benefited patients with severe TR disease (Identifier: NCT03904147).

Kodali et al. (2023) study reported one-year outcomes with the PASCAL (Edwards Lifesciences) transcatheter valve 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 (Identifier: 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 (Identifier: 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 Kansas City Cardiomyopathy Questionnaire 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.

Transcatheter Tricuspid Valve Replacement

Bugan et al. (2024) 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.

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 (Identifier: NCT04221490).

Lu et al. (2021) conducted a compassionate multicenter study conducting transcatheter tricuspid valve replacement in high-risk non-surgical candidates with severe TR. One case was unsuccessful due to right ventricle perforation, leading to a 97.8% procedural success rate. Follow up was 6 months post procedure and revealed device migration in one patient, and a 17.4% mortality rate. Transthoracic echocardiography at 6 months after operation showed TR was significantly reduced to none/trivial in 33, mild in 4, and moderate in 1. Patients who suffered from peripheral oedema and ascites decreased from 100.0% and 47.8% at baseline to 2.6% and 0.0% at 6 months. The authors concluded transcatheter tricuspid valve replacement is a feasible procedure in this population.

National and Specialty Organizations

The **American Heart Association (AHA)** and the **American College of Cardiology (ACC)** (Otto et al. 2021) 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 span 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).

The National Institute for Health and Care Excellence (NICE) issued an interventional procedure guidance [IPG731] on *Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation* stating that evidence on TTVR efficacy is limited in quality and quantity, and studies on its safety show serious complications. NICE recommends that for those with severe and symptomatic tricuspid regurgitation TTVI should on 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 is inadequate the procedures safety and efficacy in this population.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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

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

08/14/2024	Policy reviewed. No changes 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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