Medical Coverage Policy | Transcatheter Tricuspid Valve Repair or Replacement (T-TEER or TTVR)

EFFECTIVE DATE: 04|01|2026
POLICY LAST REVIEWED: 07|01|2026

OVERVIEW

Transcatheter tricuspid valve repair or replacement is an emerging alternative to surgical therapy for patients with severe tricuspid regurgitation (TR), particularly those at elevated surgical risk. TR may result from a primary structural abnormality of the tricuspid valve or, more commonly, from secondary annular dilation and leaflet tethering due to right ventricular remodeling associated with left-sided heart failure, pulmonary hypertension, or atrial fibrillation. Surgical intervention for isolated TR is often underutilized due to high perioperative risk and limited referral, highlighting a substantial unmet need for less invasive treatment options. Two transcatheter devices, TriClip™ (Abbott) and EVOQUE™ (Edwards Lifesciences), have been developed. TriClip, a transcatheter edge-to-edge repair system, is designed to reduce TR by approximating valve leaflets, while the EVOQUE system provides a complete transcatheter valve replacement through a self-expanding prosthesis anchored within the native valve structure.

This policy is applicable for Commercial Products only. For Medicare Advantage Plans, see Related Policies section.

This policy addresses the following procedures:

- Transcatheter Tricuspid Valve Edge-to-Edge Repair (T-TEER), CPT Code 0569T
- Transcatheter Tricuspid Valve Repair (TTVR), CPT Code 0646T

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Commercial Products

T-TEER and TTVR are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

For Medicare Advantage Plans, refer to the Related Policies section.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable surgery benefits/coverage.

BACKGROUND

Tricuspid Regurgitation

Tricuspid regurgitation (TR) refers to the backward flow of blood through the tricuspid valve due to inadequate closure of the valve during systole and is the most common indication requiring tricuspid valve repair or replacement. TR may be classified as primary, due to intrinsic abnormalities of the valve apparatus, or more commonly secondary (functional), caused by right ventricular remodeling and annular dilation. Common etiologies include pulmonary hypertension, left heart disease, atrial fibrillation, and the presence of cardiac implantable electronic devices. Clinically significant TR is common in older adults, affecting approximately4% of individuals over age 75 and up to 7% of those over 65, with a higher prevalence in

women. TR has been observed to be independently associated with increased mortality, heart failure hospitalizations, and reduced quality of life, even in moderate forms.

Treatment
Historically, treatment options for TR were limited to diuretics for symptom relief or surgical intervention in conjunction with other valve procedures. According to the current American College of Cardiology and the American Heart Association guidelines (ACC/AHA), the only Class 1 surgical indication for treating TR is inpatients undergoing left-sided valve surgery; with all isolated surgeries having a class 2 level of evidence. Isolated surgical tricuspid repair or replacement has been associated with high perioperative mortality of up to 10% and is infrequently pursued. Many patients are deemed inoperable due to frailty, comorbidities, or advanced disease. Until recently, there were no approved minimally invasive therapies specifically indicated for TR, leaving a large proportion of patients untreated and symptomatic despite maximal medical therapy. The emergence of transcatheter tricuspid valve interventions offers an alternative treatment with two modalities that have gained regulatory approval in the United States: transcatheter edge-to-edge repair (T-TEER) and transcatheter valve replacement (TTVR).

Regulatory Status
The Evoque™ Tricuspid Valve Replacement System (Edwards Lifesciences, Co.) and the TriClip™ G4 System (Abbott Medical) are currently the only FDA-approved devices for tricuspid valve replacement and repair. Several additional devices, the PASCAL™ Transcatheter Valve Repair System, a transcatheter edge-to-edge repair device similar to TriClip, and the Cardioband™ Tricuspid Valve Reconstruction system, an annuloplasty device, both by Edwards Lifesciences, have received CE marking but have not yet been FDA approved.

TriClip G4 System
The TriClip G4 System, manufactured by Abbott, was granted FDA Premarket Approval (PMA) on April 1, 2024. The device is indicated 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." TriClip is derived from the MitraClip system, which served as its predicate device under compassionate use for tricuspid regurgitation. The technology adapts MitraClip's TEER for use in the tricuspid position, providing a repair-based alternative to valve replacement.

Post-approval, TriClip is subject to two Post-Approval Studies (PAS). Continued Follow-up of the Premarket Cohort, which monitors Investigational Device Exemption (IDE) and Continued Access Protocol patients through 5 years, tracking clinical outcomes including mortality, TR grade, reintervention, New York Heart Association (NYHA) class, 6 minute walk test (6MWT), and quality-of-life metrics (KCCQ, SF-36). And a registry-based study involving 5,000 patients or all treated in the first 2 years, with a detailed subgroup of 1,000 patients tracked for 1-year outcomes. Data from years 2 to 5 will be supplemented via Centers for Medicare & Medicaid Services (CMS) claims, and a minimum enrollment of 100 patients per underrepresented racial/ethnic group is mandated.

EVOQUE Tricuspid Valve Replacement System
The Edwards EVOQUE Tricuspid Valve Replacement System received PMA from the FDA on February 1, 2024. The approved indication for use is, "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 is a TTVR device, and, unlike repair devices, it does not rely on annular or leaflet anatomy for efficacy, making it suitable for patients in whom repair is not feasible.

The FDA has imposed several post-approval requirements, most notably a registry-based study. This study will enroll at least 5,000 consecutively treated patients (or all patients treated within the first 2 years of approval, whichever is greater) into the Society of Thoracic Surgeons and the American College of Cardiology

(STS/ACC) Transcatheter Valve Therapy Registry. Data will be collected for at least five years post-procedure, with one-year outcomes sourced from the registry and longer-term data linked to CMS claims. A focus of the study is on underrepresented populations, requiring at least 100 patients from each racial/ethnic group, including Black, Asian, Native American, Pacific Islander, and Hispanic/Latino patients.

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

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

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

Taramasso et al (2019) reported on a large, prospective international registry which was developed to evaluate the initial clinical applications of transcatheter tricuspid valve intervention (TTVI) with different devices. TTVI for native tricuspid valve dysfunction has been emerging during the last few years as an alternative therapeutic option to serve a large high- risk population of patients with severe symptomatic tricuspid regurgitation (TR). The TriValve Registry included 312 high-risk patients with severe TR (76.4 +/- 8.5 years of age; 57% female; EuroSCORE II 9 +/- 8%) at 18 centers.

Interventions included repair at the level of the leaflets (MitraClip, Abbott Vascular, Santa Clara, California; PASCAL Edwards Lifesciences, Irvine, California), annulus (Cardioband, Edwards Lifesciences; TriCinch, 4tech, Galway, Ireland; Trialign, Mitraling, Tewksbury, Massachusetts), or coaptation (FORMA, Edwards Lifesciences) and replacement (Caval Implants, NaviGate, NaviGate Cardiac Structures, Lake Forest, California). Clinical outcomes were prospectively determined during mid-term follow-up. A total of 108 patients (34.6%) had prior left heart valve intervention (84 surgical and 24 transcatheter, respectively). TR etiology was functional in 93 percent, and mean annular diameter was 46.9 +/- 9mm. In 75 percent of the patients, the regurgitant jet was central (vena contracta 1.1 +/- 0.5; effective regurgitant orifice area 0.78 +/- 0.6 cm(2)). Pre-procedural systolic pulmonary artery pressure was 41 +/- 14.8 mm Hg. Implanted devices included: MitraClip in 210 cases, Trialign in 18 cases, TriCinch first generation in 14 cases, caval valve implantation in 30 cases, FORMA in 24 cases, Cardioband in 13 cases, NaviGate in six cases, and PASCAL in

one case. In 64 percent of the cases, TTVI was performed as a stand-alone procedure. Procedural success was defined as successful device implantation and residual TR. The report concluded that TTVI is feasible with different technologies, has a reasonable overall procedural success rate, and is associated with low mortality and significant clinical improvement. Mid-term survival of this high-risk population is favorable. The report also noted that greater coaptation depth is associated with reduced procedural success, which is an independent predictor of mortality.

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

CODING

Commercial Products

The following CPT code(s) are considered not medically necessary:

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

RELATED POLICIES

Clinical Trials Medicare Advantage Plans
Medicare Advantage Plans National and Local Coverage Determinations

PUBLISHED

Provider Update, February/September 2026

REFERENCES

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