2.02.34	Transcatheter Tricuspid Valve Repair or Replacement		
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Policy Statement

I. Transcatheter tricuspid edge to edge repair (T-TEER) with a device approved by the U.S. Food and Drug Administration (FDA) for use in tricuspid valve repair may be considered **medically necessary** for individuals with severe tricuspid regurgitation (TR) despite the use of maximally tolerated guideline-directed medical therapy who are considered at intermediate or high risk for open surgery as assessed by a heart team (see Policy Guidelines section).

II. Transcatheter tricuspid valve replacement (TTVR) with a device approved by the U.S. FDA may be considered **medically necessary** for individuals with severe TR despite the use of maximally tolerated guideline-directed medical therapy who are TTVR candidates as identified by a heart team (see Policy Guidelines section).

III. T-TEER and TTVR are considered **investigational** in all other situations.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The FDA definition of intermediate or high risk for open surgery is:

- High risk: Society of Thoracic Surgeons (STS) predicted operative risk score of 8% or higher or judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.
- Intermediate risk: STS predicted risk of mortality between 3% and 7%.

Moderate to severe or severe tricuspid regurgitation (TR) may be defined by echocardiography; for definitions, see Appendix Table 1.

Optimal medical therapy may be determined by guidelines from specialty societies (e.g., American Heart Association/American College of Cardiology Guideline for the Management of Patients with Valvular Heart Disease or European Society of Cardiology/European Association for Cardio-Thoracic Surgery Guidelines for the Management of Valvular Heart Disease [refer to supplemental materials for guideline citations]).

The composition of a heart care team should include, at minimum, the following: cardiac surgeon, interventional cardiologist, cardiologist with training and experience in heart failure management, electrophysiologic, multi-modality imaging specialists, and interventional echocardiographic. Individuals treated with TriClip or Evoque should be part of continuing evidence development: studies must report 24-month outcomes (mortality, hospitalizations, or composite), use an active comparator, include a care management plan detailing heart team roles, and be designed to allow subgroup analyses by demographics, clinical factors, and provider characteristics.

Contraindications

The TriClip system is contraindicated in patients with intolerance (including allergy or untreatable hypersensitivity) to procedural anticoagulation, untreatable sensitivity to nickel-titanium alloy or cobalt-chromium alloy, or active endocarditis or other active infection of the tricuspid valve.

Evoque is contraindicated in individuals with active endocarditis or other active infection requiring antibiotic therapy (oral or intravenous); untreatable hypersensitivity or contraindication to any of the following: all antiplatelets, all anticoagulants, nitinol alloys (nickel and titanium), bovine tissue, glutaraldehyde, contrast media, or transesophageal echocardiography; tricuspid valve anatomy that precludes proper device deployment and functionality based on CT and echocardiographic evaluation. Patients must be able to tolerate at least one antiplatelet medication AND one anticoagulant medication.

Coding

See the Codes table for details.

Description

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 to address this gap. 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. Both devices are intended for patients with severe symptomatic TR who are not suitable candidates for surgery and continue to experience symptoms despite optimized medical therapy.

Summary of Evidence

The evidence for the use of TriClip in patients with symptomatic tricuspid regurgitation (TR) considered candidates for transcatheter tricuspid edge-to-edge repair (T-TEER) includes 2 RCTs (TRILUMINATE and Tri.Fr), a prospective single-arm of the TRILUMINATE study, several database or real-world registry studies, and multiple additional case series. The initial TRILUMINATE RCT demonstrated that TriClip plus guideline-directed medical therapy significantly improved a composite primary outcome measure of all-cause mortality, tricuspid valve surgery, hospitalization for heart failure (HFH), and improvements of ≥ 15 points on the Kansas City Cardiomyopathy Questionnaire (KCCQ) compared to guideline-directed medical therapy alone. This finding was primarily driven by changes in KCCQ scores, and no significant differences in mortality or HFH was observed. However, TR severity was significantly reduced in the T-TEER group, and safety outcomes were favorable at 30 days. The expanded TRILUMINATE cohort confirmed these findings, with a higher win ratio and improved secondary endpoints, including 6-minute walk distance and KCCQ score. Analysis of this cohort at 2 years showed a durability of effect for the reduction in TR severity as well as improvements in KCCQ scores, and, unlike assessments at earlier timepoints, demonstrated an improvement in the rate of annual HFHs. However, both analyses were limited by a lack of blinding, a reliance on subjective measures, and a maximal follow-up duration of 2 years. The Tri.Fr trial, an independent RCT, also reported significant improvements in composite functional outcomes, TR severity, and KCCQ scores at 1 year, although the trial had similar limitations. The TRILUMINATE single-arm study demonstrated sustained reductions in TR and functional improvement over 3 years with an acceptable safety profile. Similarly, the bRIGHT registry showed meaningful improvements in TR severity, NYHA class, and KCCQ scores at 1 year in a high-risk, real-world cohort. Across the 3

retrospective registry and database studies, T-TEER, including both FDA-approved and investigational devices, was associated with favorable safety outcomes including significantly lower in-hospital mortality, reduced acute kidney injury, and fewer perioperative complications compared to surgical or conservative management; however, a mortality benefit at 1-year follow-up was observed in only a single study, and limited to patients with intermediate-stage disease receiving T-TEER compared to medical therapy. Collectively, these studies suggest TriClip provides symptomatic benefit in select patients with severe TR with a reduction in the rate of HFH; the absence of long-term comparative data and reliance on primarily patient-reported outcomes underscore the need for additional longer-term follow-up and continued evidence development. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

The evidence for the use of the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in patients with symptomatic tricuspid regurgitation (TR) includes a single-arm feasibility study (TRISCEND), a pivotal randomized controlled trial (TRISCEND II), and several additional case series. The TRISCEND study demonstrated that the EVOQUE device could be safely implanted in a high-risk population, with high procedural success and significant improvements in TR severity, functional status, and quality of life measures at 1 year. However, the study lacked a control group and had a high rate of major adverse events, primarily due to severe bleeding and pacemaker implantation, limiting the strength of its conclusions regarding comparative effectiveness. The subsequent TRISCEND II trial, a multicenter RCT, found that TTVR with EVOQUE significantly improved a hierarchical composite endpoint compared to medical therapy alone, with greater improvements in Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, New York Heart Association (NYHA) class, and 6-minute walk distance. Although the device group showed numerically lower rates of mortality and heart failure hospitalization, the trial was not powered to detect differences in these individual clinical outcomes. TR reduction to mild or less was achieved in over 95% of patients receiving the device versus 2.3% of controls. The EVOQUE group in TRISCEND II also experienced higher rates of severe bleeding and new unplanned pacemaker implantation, raising safety considerations. Limitations of the RCT include reliance on patient-reported outcomes within a hierarchical composite, differential attrition between groups, limited duration of follow-up, and control group crossover, which may bias interpretation of results. While these early results are promising, additional long-term data from comparative trials are needed to confirm the clinical durability and safety profile of EVOQUE relative to other surgical approaches. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Related Policies

- Transcatheter Aortic-Valve Implantation for Aortic Stenosis
- Transcatheter Mitral Valve Repair or Replacement

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

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. The focus of this review will be on devices that have FDA approval.

TriClip G4 System

The TriClip G4 System, manufactured by Abbott, was granted FDA Premarket Approval (PMA) on April 1, 2024 (P230007; product code NPS). 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.[6,]

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 (P230013; product code NPW). 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.[7,]

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.

Rationale

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.[1,] 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.[2,] Clinically significant TR is common in older adults, affecting approximately 4% of individuals over age 75 and up to 7% of those over 65, with a higher prevalence in women.[2,] TR has been observed to be independently associated with increased mortality, heart failure hospitalizations, and reduced quality of life, even in moderate forms.[3,]

Treatment

Historically, treatment options for TR were limited to diuretics for symptom relief or surgical intervention in conjunction with other valve procedures.[4,] 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 in patients 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.[5,] 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).

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Tricuspid Valve Repair with TriClip

Clinical Context and Therapy Purpose

The purpose of tricuspid transcatheter edge-to-edge repair (T-TEER) using TriClip in individuals who have severe primary or secondary tricuspid regurgitation (TR) despite optimal medical management and are at intermediate or greater risk for surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with symptomatic severe primary or secondary TR at an intermediate or greater risk for surgery for whom tricuspid valve repair is deemed appropriate by a heart team.

Interventions
The therapy being considered is TriClip. TriClip uses a T-TEER approach to treat TR by mechanically grasping and approximating the valve leaflets. Delivered via transfemoral venous access and guided by transesophageal echocardiography, the device positions a clip between the leaflets creating a double orifice that purports to improve leaflet coaptation and reduce the regurgitant orifice area.

Comparators
Comparators of interest are guideline-directed medical management and surgical tricuspid valve repair and replacement. Surgical tricuspid valve repair is typically performed through open-heart surgery, and the decision to repair or replace a damaged tricuspid valve depends on the severity of TR or stenosis, as well as the individual's age, symptoms, right heart function, and overall health status.

Outcomes
The general outcomes of interest are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. A summary of outcome scales and classifications relevant to the reviewed evidence base for TR is presented in Table 1.

Table 1. Health Outcome Measures Relevant to Tricuspid Valve Repair and Replacement

Outcome	Measure (Units)	Description and Administration	Thresholds for Improvement/Decline or Clinically Meaningful Difference (if known)
Kansas City Cardiomyopathy Questionnaire (KCCQ)	Continuous scale (0-100); higher scores indicate better health status.	The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a validated, patient-reported outcome measure designed to assess physical function, symptoms, social limitation, and quality of life in individuals with heart failure. Two versions are available: the standard version with 23 items and a short version with 12 items. Items assess the presence of symptoms or limitations in the last 2 weeks. Scores of 0 to 24 indicate very poor to poor quality of life; 25 to 49, poor to fair; 50 to 74, fair to good; and 75 to 100, good to very good.	A change of 5 points or more on the KCCQ is considered the minimal clinically important difference (MCID), with increases of 10 and 20 points reflecting moderate and large improvements, respectively.[8,]
NYHA Class	Ordinal variable (Class I-IV); higher classes indicate greater physical limitations and worse symptoms.	The New York Heart Association (NYHA) functional classification is a clinician-rated measure of functional limitation due to heart failure, based on patient-reported symptoms during physical activity: Class I - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath	No specific MCID was identified for NYHA, but each class reflects a meaningful change in patient limitations.

Outcome	Measure (Units)	Description and Administration	Thresholds for Improvement/Decline or Clinically Meaningful Difference (if known)
		when walking, climbing stairs etc. Class II - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity. Class III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20—100 m).Comfortable only at rest. Class IV - Severe limitations. The individual experiences symptoms even while at rest. Mostly bedbound patients.	
Tricuspid Regurgitation (TR)	Ordinal variable (5 classes); higher classes indicate worse tricuspid regurgitation.	Tricuspid regurgitation (TR) severity is assessed via echocardiography and reflects the degree of backward blood flow through the tricuspid valve. It is typically categorized into several classes: none, mild, moderate, severe, massive, and torrential (See Appendix Table 1).	No specific MCID was identified for TR, but each class reflects a meaningful change in regurgitation.
6-Minute Walk Test (6MWT) (meters)	Continuous variable (meters walked during 6 minutes: Normal ranges vary based on age, sex, height, and weight but range between 400 to 700 meters for healthy adults). Longer distances indicate better functional status.	The 6-Minute Walk Test (6MWT) is a standardized measure of submaximal exercise capacity. It assesses the distance a patient can walk on a flat surface over a 6-minute period.	In patients with heart failure, a change of approximately 30 meters in walking distance is regarded as a minimally clinically important difference.[9,]
Patient Global Assessment (PGA) Score	Ordinal scale (7 points); higher scores indicate better patient-perceived benefit.	The Patient Global Assessment (PGA) is a single-item, patient-reported measure of overall health status or perceived change in disease severity. It typically asks patients to rate their overall condition or improvement on a Likert-type scale or visual analog scale (VAS). The PGA often uses a 7-point ordinal scale ranging from "very much worse" to "very much improved.	No specific MCID was identified for PGA, but improvements of 1 point have been correlated to roughly 5 points on the KCCQ, which was determined to be an MCID.[10,]

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

The TRILUMINATE trial (NCT03227757) was a prospective, multicenter, RCT that enrolled 350 patients across 65 centers in the United States, Canada, and Europe.[11] Patients were randomized 1:1 to receive either tricuspid T-TEER with the TriClip device plus guideline-directed medical therapy or guideline-directed medical therapy alone. Eligible participants were 78 years of age on average, predominantly female (54.9%), and symptomatic (NYHA class II-IVa) with severe TR confirmed by an independent echocardiographic core laboratory (see Table 2). Patients had to be on stable medical therapy for at least 30 days and deemed at intermediate or greater surgical risk by a local heart team. The primary endpoint was a hierarchical composite of all-cause mortality or tricuspid valve surgery, heart failure hospitalization (HFH), and a clinically meaningful improvement (≥15 points) in Kansas City Cardiomyopathy Questionnaire (KCCQ) score at 1 year using a win ratio methodology. The trial met its primary endpoint with a win ratio of 1.48 (95% CI [confidence interval], 1.06 to 2.13; p=.02), indicating that patients treated with the TriClip device experienced a significantly greater benefit on the composite outcome compared to controls, which was largely driven by improvements in the KCCQ score (see Table 3). While no significant differences were observed in mortality or HFH, patients in the T-TEER group had a mean KCCQ score improvement of 12.3 points versus 0.6 in the control group (p<.001). At 30 days, 87% of the T-TEER group had TR reduced to moderate or less, compared to 4.8% in controls (p<.001). A total of 98.3% of patients were free from major adverse events at 30 days. Limitations included a short duration of follow-up, lack of blinding for participants, absence of improvement in mortality and HFH elements of the composite endpoint, and achievement of the primary outcome measure largely driven by a patient-reported outcome (see Tables 4 and 5).

Tang et al. (2025) reported outcomes from the full TRILUMINATE randomized cohort, expanding enrollment to 572 patients across 68 centers.[12] The study maintained the same design and eligibility criteria as Sorajja et al. 2023 and continued enrollment beyond the primary analysis population as part of the trial's adaptive design (see Table 2). In the full cohort, the primary endpoint again favored the T-TEER group, with a win ratio of 1.84 (p<.0001). Although no difference was observed in freedom from all-cause mortality or TR surgery (90.6% vs. 89.9%; p=.82) or in HFH (0.17 vs. 0.20 events/patient-year; p=.40), the proportion of patients achieving a ≥15-point improvement in KCCQ score was significantly higher in the T-TEER group (52.3% vs. 23.5%; p<.0001). Secondary endpoints also favored T-TEER, including TR severity reduction to moderate or less at 30 days (88.9% vs. 5.3%; p<.0001), mean KCCQ score improvement (13.0 vs. -0.5 points; p<.0001), and 6-minute walk distance (+1.7 m vs. -27.4 m; p<.0001). Freedom from major adverse events was 98.9% in the device group, exceeding a pre-specified performance goal of 90%. Despite these favorable outcomes, limitations remained consistent with the earlier report: limited follow-up duration, lack of blinding, and reliance on subjective endpoints. Additionally, post-hoc subgroup comparisons and unadjusted multiplicity in secondary outcomes may influence the interpretation of statistical significance.

Kar et al. (2025) reported the 2-year outcomes of the full TRILUMINATE cohort.[13] The prespecified 2-year endpoints were recurrent HFH and freedom from a modified composite outcome of all-cause mortality, tricuspid valve surgery, or T-TEER intervention. By the 2-year follow-up, only 57 participants remained in the control group receiving guideline-directed medical therapy alone, although most comparisons used an intent-to-treat analysis. This reduction was due to 49% (n=142) of eligible control participants crossing over to T-TEER at 1 year, 11 deaths occurring prior to 2 years, 16 participant withdrawals, 6 individuals undergoing tricuspid valve surgery, and 12 participants missing their 2-year follow-up assessment. Individuals who crossed over to T-TEER were more likely to be symptomatic, with a higher proportion in NYHA class III/IV (47% vs 30%), and more frequently exhibited torrential TR (65% vs 42%) compared to those who did not cross over. The trial met its primary 2-year endpoint, demonstrating a significant 28% relative risk reduction in recurrent HFH in

the T-TEER group compared to control (Hazard Ratio [HR] 0.72; p=.02), and a significant difference when comparing annualized HFH event rates (0.19 vs. 0.26 events/patient-year; p=.02). Freedom from the composite endpoint was 77.6% (95% CI: 72.2% to 82.1%) in the T-TEER group versus 29.3% (95% CI: 23.8% vs. 34.9%; p<.0001) in control participants driven by crossover of eligible patients to T-TEER, although both all-cause mortality and valve surgery rates remained similar. At 2 years, 84% of T-TEER individuals had TR severity reduced to moderate or less, and the mean KCCQ score improved by 15.4 points from baseline. Adverse event rates were low and included: stroke (1.9%), transient ischemic attack (1.7%), tricuspid valve surgery (2.3%), cardiogenic shock (0.4%), and permanent pacemaker implantation (5.5%). In the crossover group, comparable improvements in HFH rates, KCCQ scores, and TR severity were observed, along with similarly low adverse event rates at the 1-year follow-up. Limitations included high crossover in the control arm after 1 year, which diminished the size of the pure control group and potentially created a selection bias where sicker patients with more uncontrolled TR were likelier to crossover.

Donal et al. (2025) presented the Tri.Fr randomized clinical trial (NCT04646811), an independent, investigator-initiated study conducted across 24 centers in France and Belgium.[14] This 1:1 randomized trial compared T-TEER plus medical therapy to medical therapy alone in 300 patients with severe symptomatic TR. Participants had a mean age of 78 years, and most had either massive (63%) or torrential (28%) TR at baseline. The primary endpoint was a composite outcome at 1 year, incorporating NYHA class change, patient global assessment (PGA) change (>4 points), and major cardiovascular hospitalization or death, which was assessed by a blinded adjudication committee. The primary endpoint was achieved in 74.1% of the T-TEER group versus 40.6% in the control group (p<.001). At 1 year, only 6.8% of T-TEER-treated patients had massive or torrential TR compared to 53.5% of controls (p<.001). The mean KCCQ score at 1 year was significantly higher in the T-TEER group (69.9 vs. 55.4; p<.001), and the composite win ratio for secondary endpoints (time of death, time of secondary tricuspid valve surgery, heart failure hospitalization, KCCQ improvement, freedom from MACE, freedom from CV death) tested hierarchically was 2.06 (95% CI, 1.38 to 3.08; p<.001), favoring T-TEER. Procedural success was high (97.3%), and adverse events were infrequent and similar between groups. Limitations of the Tri.Fr trial include its unblinded design, reliance on subjective outcome measures, exclusion of patients with concomitant valve disease, and a relatively short 1-year follow-up.

Table 2. Summary of Key TriClip RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Sorajja et al (2023);[11] TRILUMINATE Primary Analysis	Canada, EU, US	65	2019-2022	Symptomatic severe tricuspid regurgitation Mean age: 78 yrs NYHA Class III or IV: 57.4% Torrential TR Severity: 50.9%	TriClip plus medical therapy (N=175)	Medical therapy alone (N=175)
Tang et al (2025);[12] TRILUMINATE Full Randomized Cohort; Kar et al (2025)[13] 2 year follow-up	Canada, EU, US	68	2019-2022	Symptomatic severe tricuspid regurgitation Mean age: 78 yrs NYHA Class III or IV: 44.9% Torrential TR Severity: 50.1%	TriClip plus medical therapy (N=285)	Medical therapy alone (N=287)
Donal et al (2024);[14] Tri.Fr	EU	24	2021-2024	Symptomatic severe tricuspid regurgitation	TriClip plus medical	Medical therapy alone (N=148)

Study; Trial	Countries	Sites	Dates	Participants	Interventions
				Mean age: 78 yrs NYHA Class III or IV: 42.3% Torrential TR Severity: 28%	therapy (N=152)

NYHA: New York Heart Association class; TR: tricuspid regurgitation. RCT: randomized controlled trial.

Table 3. Summary of Key TriClip RCT Results

Study	Hierarchical Win Ratio at 1 yr[1]	KCCQ, change from BL to 1 yr	NYHA class I or II at 1 yr	TR (no greater than moderate) at 30 days	6MWT, change from BL to 1 yr	Freedom from major AE at 30 days	Mortality at 1 yr
Sorajja et al (2023);[11]	350	350	347	350	350	175	350 All-cause Mortality:
TriClip + Medical Therapy	11348	12.3 ± 1.8	125 (83.9%)	140 (87%)	-8.1 ± 10.5	98.3	9.4%
Medical Therapy	7643	0.6 ± 1.8	88 (59.5%)	7 (4.8%)	-25.2 ± 10.3	NR	10.6%
Diff (95% CI)	1.48 (1.06 to 2.13; p=.02)	11.7 (6.8 to 16.6; p<.001)	NR, similar rates at BL	p<.001	17.1 (-12 to 46.1; p=.25)	(96.3 to 100; p<.001)	NS
Tang et al (2025);[12]	572	497	572	514	435	281	572 All-cause Mortality:
TriClip + Medical Therapy	31991	13 ± 1.4	85% (p<.0001 vs BL)	240 (88.9%)	1.7 ± 7.5	98.9	90.6%
Medical Therapy	17388	-0.5 ± 1.4	61% (p<.01 vs BL)	13 (5.3%)	-27.4 ± 7.4	NR	89.9%
Diff (95% CI)	1.8 (1.4 to 2.5; p<.0001)	13.5 (9.5 to 17.5; p<.0001)	NR	p<.0001 in T-TEER group; p=.11 in medical therapy	31.8 (12.9 to 50.6; p<.0001)	(97.7 to 100; p<.0001)	p=.82
Kar et al (2025)[13]	2 yr outcomes: Hierarchical composite endpoint, freedom from: all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention	KCCQ change at 2 yrs:	Annualized HFH (events/patient-year)				Mortality at 2 yrs
TriClip + Medical Therapy	77.6%	15.4 ± 23.4	.19 (0.15 to 0.23)	84%	NR		82.1%
Medical Therapy	29.3%	NR	.26	63%	NR		82.9%
Diff (95% CI)	p<.0001	NR	p=.02	NR, control arm includes crossover individuals	NR		NS

Study	Hierarchical Win Ratio at 1 yr[1]	KCCQ, change from BL to 1 yr	NYHA class I or II at 1 yr	TR (no greater than moderate) at 30 days	6MWT, change from BL to 1 yr	Freedom from major AE at 30 days	Mortality at 1 yr
Donal et al (2024);[14]	290	272	290 Improved Clinical Composite Score at 1 yr	260, at 1 yr	263 Improved PGA at 1 yr:	290 Freedom from MACE at 1 yr:	290 CV Mortality at 1 yr:
TriClip + Medical Therapy	9285	15.9 (30.1)	74.1%	104 (78.3%)	74.6%	84.4%	3.4%
Medical Therapy	4504	0.40 (25.7)	40.6%	14 (11%)	39.5%	80.1%	5.8%
Effect estimate (95% CI)	2.06 (1.38 to 3.08; p<.001)	14.5; p<.001	0.67 (0.61 to 0.72; p<.001)	0.73 (0.68 to 0.78; p<.001)	0.68 (0.63 to 0.74; p<.001)	0.78 (0.45 to 1.36; p=.38)	0.60 (0.20 to 1.84; p=.37)

6MWT: 6 Minute Walk Test; AE: Adverse events; BL: baseline; CI: confidence interval; CV: cardiovascular; KCCQ: Kansas City Cardiomyopathy Questionnaire; MACE: major adverse cardiovascular events; NR: not reported; NS: not significant; NYHA: New York Heart Association class; PGA: patient global assessment; T-TEER: transcatheter tricuspid edge to edge repair; TR: tricuspid regurgitation.

[1] death from any cause or tricuspid valve surgery; hospitalization for heart failure; and improvement of ≥15 points in KCCQ score at 1 yr.

Tables 4 and 5 display notable gaps identified in TRILUMINATE and TRI.FR. Design and conduct gaps in both trials include their open-label design, exclusion of patients with concomitant valve disease and limited duration of follow-up. Lack of blinding is less of a concern with objective outcome measures but could impact the validity of measures of symptoms and quality of life.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Sorajja et al (2023);[11] Tang et al (2025);[12] Kar et al (2025)[13]	5. Participants were defined as intermediate or high surgical risk by local heart teams; no presentation of surgical risk stratification in patient characteristics		5. Participants were allowed to cross-over after 1 year in the control arm; a high proportion of patients crossed over at this time, which may create selection bias for who remained in the control arm (those that remained in the pure control arm were less symptomatic and had better TR than those who crossed over)		

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Donal et al (2024);[14,]	3. Exclusion of patients with concomitant valve disease				2. 1 year follow-up only

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Sorajja et al (2023);[11,];Tang et al (2025);[12,]		1: Patients and study staff not blinded; tricuspid regurgitation severity and adverse events assessed by blinded committee			2: Post-hoc analysis of RCT: not powered to detect differences subgroup analyses	2. Multiplicity corrections not performed for secondary outcomes in the full-cohort study by Tang et al (2025)
Donal et al (2024);[14,]		1: Patients and study staff not blinded; Primary composite measure, tricuspid regurgitation severity and adverse events assessed by blinded committee				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

The three retrospective studies, Mohamed et al (2023), Schlotter et al (2025), and Shimoda et al (2025), analyzed outcomes of transcatheter versus surgical tricuspid valve repair or medical management alone using large databases and registries.[15,16,17,] All studies were limited by a lack of stratified outcomes by specific T-TEER device, and studies included a mix of MitraClip, TriClip, and PASCAL systems.

The prospective, multicenter European Tricuspid Regurgitation and Repair registry (EuroTR) was conducted across 12 centers in Europe from 2016 to 2022.[16,] The study enrolled 1,885 patients with symptomatic severe TR, including 1,300 treated with transcatheter edge-to-edge repair (T-TEER) using TriClip or PASCAL, and 585 conservatively managed with medication alone. Patients were categorized into early (21%), intermediate (62%), and advanced (17%) TR disease stages based on biventricular function, renal function, and natriuretic peptide levels. The median age was 79 years, and NYHA class III/IV symptoms were present in >85% of the cohort. One-year mortality was 6%, 15%, and 31% for early, intermediate, and advanced stages, respectively. In the intermediate-stage subgroup, 1-year mortality was significantly lower with T-TEER compared to conservative management (13% vs. 21%; Hazard Ratio [HR] 0.73, 95% CI: 0.52 to 0.99; p=0.03). No significant mortality difference was observed in early or advanced stages. Procedural success (defined as residual TR ≤ grade 2) was 83% overall in T-TEER-treated individuals and did not differ by disease stage.

The retrospective, observational study by Shimoda et al (2025) was conducted using a sample of Medicare beneficiaries in the United States.[17,] The study analyzed 1,143 patients aged 65 to 99 years with symptomatic TR who underwent either T-TEER (n=409) or isolated surgical tricuspid repair (STVR, n=734) between July 2016 and December 2020. Participants in the T-TEER group and STVR group had similar ages, comorbidities, and frailty scores after propensity matching. The 2-year all-cause mortality was comparable between groups (adjusted hazard ratio [HR] 0.84; 95% CI, 0.63 to 1.13; p=.25). T-TEER was associated with significantly lower in-hospital mortality (2.5% vs. 12.5%, p<.001), permanent pacemaker implantation (0.0% vs. 12.7%, p<.001), acute kidney injury (11.9% vs. 33.8%, p<.001), and cardiogenic shock (4.0% vs. 17.1%, p<.001). The median hospital stay was also shorter in the T-TEER group (2 vs 11 days, p<.001), with more patients discharged home (88.4% vs. 48.4%). However, tricuspid valve reintervention was significantly more frequent in the T-TEER group (HR, 8.03; 95% CI, 2.87 to 22.48; p<.001).

A retrospective, population-based study using the U.S. National Inpatient Sample (NIS) was conducted to compare inpatient outcomes of transcatheter versus surgical tricuspid valve repair.[15,] This study included 37,115 hospitalized patients with TR from 2016 to 2020, of whom 1,830 (4.9%) underwent T-TEER and 35,285 (95.1%) underwent STVR. Following 1:2 propensity-score matching, 1,520 T-TEER and 2,920 STVR cases were analyzed. After matching, T-TEER patients remained older (mean 76 vs 64 years) and more likely to have co-morbid conditions. T-TEER was associated with significantly lower inpatient mortality (3.0% vs 6.7%; adjusted odds ratio [aOR] 0.43; 95% CI: 0.31 to 0.59; p<.01), fewer cardiovascular complications (8.2% vs 19.5%; aOR 0.37; 95% CI: 0.30 to 0.45; p<.01), fewer renal complications (24.0% vs 36.1%; aOR 0.56; 95% CI: 0.45 to 0.64; p<.01), fewer infectious complications (4.9% vs 10.6%; aOR 0.44; 95% CI: 0.34 to 0.57; p<.01), reduced need for mechanical circulatory support (2.0% vs. 8.4%; aOR 0.22; 95% CI: 0.15 to 0.32; p<.01), and a shorter mean hospital stay (7 vs. 15 days; p<.01). No significant differences in major bleeding or cardiac arrest were observed.

The prospective, multicenter TRILUMINATE single-arm study was conducted across 21 sites in Europe and the United States.[18] The trial enrolled 98 patients with symptomatic moderate or greater TR who were at high surgical risk and deemed suitable for leaflet repair. Participants had a mean age of 77.5 years, and 66% were female (see Table 6). A large proportion of participants were NYHA class III/IV (76%). TR severity was torrential in 33.7%, massive in 28.6%, and severe in 32.7%. The mean EuroSCORE II was 8.3%. At 3 years, 79% of subjects with evaluable echocardiograms (n=61) achieved TR reduction to moderate or less, while 92% demonstrated at least one-grade improvement. This benefit was sustained from 1 to 3 years (p=.912). Functional improvements were also maintained: NYHA class III/IV status declined from 76% at baseline to 19% at 3 years (p<.0001), and mean KCCQ scores showed a sustained improvement of 10 points from baseline (p=.006). The cumulative rate of major adverse events was 25% at 3 years, including cardiovascular mortality in 18.8%, stroke in 4.2%, and renal failure in 8.3%. No device-related surgeries, device embolizations, or cases of endocarditis were reported.

The bRIGHT registry is a prospective, single-arm, open-label study that enrolled 511 patients at 26 sites across Europe.[19] Participants had a mean age 79 years, with high comorbidity burden: 80% were NYHA class III/IV, 88% had massive or torrential TR, and 40% had chronic kidney disease. The average EuroSCORE was 7.6%. At 1 year, TR severity was reduced to moderate or less in 81% of patients with paired echocardiographic data. KCCQ scores improved by a mean of 19 points (p<.0001), and 75% of patients improved to NYHA class I/II from 21% at baseline (p<.0001). HFH rates declined significantly, and functional gains were sustained from 30 days through 1 year (see Table 7). All-cause mortality was 15.1%, cardiovascular mortality was 8.8%, and heart failure hospitalization occurred in 15.3% of patients. Major bleeding occurred in 10.8%, while tricuspid valve reintervention was needed in 3.5%.

Multiple additional case series evaluating T-TEER using the TriClip device were identified. Study populations ranged from 21 to 145 patients, with the majority being elderly (mean or median age typically around 78 years) and nearly all presenting with severe TR and NYHA functional class III or higher at baseline. [20,21,22,23,24,25,26,27] Procedural success, defined as device implantation with at least one-grade reduction in TR, was consistently high across studies, ranging from 82% to 100%, with TR severity reduced to moderate or less in 79% to 91% of patients by discharge or short-term follow-up. Outcomes were generally favorable, with improvements in NYHA class and KCCQ quality-of-life scores persisting through 1-year follow-up. Complication rates were low, with TEER-related complications occurring in 0 to 3.1% of cases, and few serious adverse events reported overall. Authors noted that anatomical factors, such as a 4-leaflet tricuspid valve configuration and larger coaptation gaps, were associated with higher rates of residual TR, emphasizing the importance of patient selection.

Table 6. Summary of Key T-TEER Non-Randomized Studies Characteristics

Study	Country	Participants	Treatment Delivery[1]	Follow-Up
Schlotter et al (2025)[16]	EU (12 sites)	A prospective, multicenter, European registry evaluating outcomes of T-TEER (TriClip or PASCAL) versus medical management stratified by TR disease stages. Mean age: 79 ± 7 EuroSCORE II: Not reported TR > Severe: 88% NYHA Class III or IV: >85%	Propensity score matched: TriClip plus medical management (n=1300) Medical management (n=585)	1 year

Study	Country	Participants	Treatment Delivery[1]	Follow-Up
Shimoda et al (2025)[17],	US (Medicare fee-for-service database)	A retrospective analysis of U.S. Medicare claims comparing T-TEER (TriClip, MitraClip, PASCAL) to surgical repair in older adults with TR. Median age: 81 (T-TEER), 74 (surgery) EuroSCORE II: Not reported TR > Severe: Not reported	Propensity score matched: TriClip plus medical management (n=409) Surgical repair (n=734)	2 years
Mohamed et al (2023)[15],	US (NIS database)	A retrospective, population-based analysis from the National Inpatient Sample comparing inpatient outcomes of T-TEER and surgical repair. Mean age: 76 (T-TEER), 64 (surgical) EuroSCORE II: Not reported TR > Severe: Not directly reported	Propensity score matched: TriClip plus medical management (n=1520) Surgical repair (n=2920)	Inpatient only
Lurz et al (2024);[19], bRIGHT	EU (26 sites)	A prospective, multicenter, open-label registry of the TriClip system for post-market valuation of safety and performance. Mean age: 79±7 EuroSCORE II: 7.6 ± 8 TR > Severe: 88% Secondary TR: 90% NYHA Class III or IV: 80%	TriClip plus medical therapy (N=511)	1 year
Nickenig (2024);[18], TRILUMINATE	US, EU (21 sites)	Individuals with symptomatic TR who were undergoing T-TEER (mean age, 79 years; NYHA class III or IV, 80%)	TriClip plus medical therapy (N=98)	3 years

NYHA: New York Heart Association class; T-TEER: transcatheter tricuspid edge to edge repair; TR: tricuspid regurgitation. RCT: randomized controlled trial.
[1]If there are multiple delivery methods or technologies then list name; mode of delivery; dose (frequency/duration). Otherwise this column can be removed.

Table 7. Summary of Key TriClip Non-Randomized Studies Results

Study	Treatment	KCCQ, change from BL	NYHA class I or II	TR (no greater than moderate)	Mortality	HFH
Schlotter et al (2025)[16],	T-TEER (n=1885)			1 yr: 83%	All-Cause Early Stage Disease, HR 1 yr: 0.78;	

Study	Treatment	KCCQ, change from BL	NYHA class I or II	TR (no greater than moderate)	Mortality	HFH
	Medical Management (n=585)				95% CI: 0.34 to 1.80; p =.54 All-Cause Intermediate Stage Disease, HR 1 yr: 0.73; 95% CI: 0.52 to 0.99; p =.03, favoring T-TEER All-Cause Advanced Stage Disease, HR 1 yr: 1.06; 95% CI: 0.71 to 1.60; p =.78	
Shimoda et al (2025)[17],	T-TEER (n=409) STVR (n=734)				Inpatient mortality: T-TEER: 2.5% STVR: 12.5%; p<.001 All-cause, HR 2 yrs: 0.84; 95% CI: 0.63 to 1.13; p=NS	NS difference
Mohamed et al (2023)[15],	T-TEER (n=1520) STVR (n=2920)				Inpatient mortality: aOR: 0.43; 95% CI: 0.31 to 0.59; p<.01	
Lurz et al (2024);[19], bRIGHT	TriClip (N=511)	1 yr: 19 ± 26 (p<.0001)	BL: 20% 1 yr: 75% (p<.0001)	BL: 2% 1 yr: 81% (p<.0001)	CV, 1 yr: 8.8% All-Cause, 1 yr: 15.1%	1 yr: 15.3%
Nickenig (2024);[18], TRILUMINATE	TriClip (N=98)	3 yrs: 10 ± 3; p=.006	3 yrs: 82% (p<.0001)	3 yrs: 79% (p=.0001)	All-Cause, 3 yrs: 27%	3 yrs: 75% reduction from BL (p<.0001)

aOR: adjusted odds ratio; BL: baseline; CI: confidence interval; CV: cardiovascular; HR: hazard ratio; STVR: surgical tricuspid valve repair; TEER: transcatheter edge to edge repair; TR: tricuspid regurgitation. RCT: randomized controlled trial.

Section Summary: Tricuspid Valve Repair with TriClip

The evidence for the use of TriClip in patients with symptomatic tricuspid regurgitation (TR) considered candidates for transcatheter tricuspid edge-to-edge repair (T-TEER) includes 2 RCTs (TRILUMINATE and Tri.Fr), a prospective single-arm of the TRILUMINATE study, several database or real-world registry studies, and multiple additional case series. The initial TRILUMINATE RCT demonstrated that TriClip plus guideline-directed medical therapy significantly improved a composite primary outcome measure of all-cause mortality, tricuspid valve surgery, hospitalization for heart failure (HFH), and improvements of ≥ 15 points on the Kansas City Cardiomyopathy Questionnaire (KCCQ) compared to guideline-directed medical therapy alone. This finding was primarily driven by changes in KCCQ scores, and no significant differences in mortality or HFH was observed. However, TR severity was significantly reduced in the T-TEER group, and safety outcomes were favorable at 30 days. The expanded TRILUMINATE cohort confirmed these findings, with a higher win ratio and improved secondary endpoints, including 6-minute walk distance and KCCQ score. Analysis of this cohort at 2 years showed a durability of effect for the reduction in TR severity as well as improvements in KCCQ scores, and, unlike assessments at earlier timepoints, demonstrated an improvement in the rate of annual HFHs. However, both analyses were limited by a lack of blinding, a reliance on subjective measures, and a maximal follow-up duration of 2 years. The Tri.Fr trial, an independent RCT, also reported significant improvements in composite functional outcomes, TR severity, and KCCQ scores at 1 year, although the trial had similar limitations. The TRILUMINATE single-arm study demonstrated sustained reductions in TR and functional improvement over 3 years with an acceptable safety profile. Similarly, the bRIGHT registry showed meaningful improvements in

TR severity, NYHA class, and KCCQ scores at 1 year in a high-risk, real-world cohort. Across the 3 retrospective registry and database studies, T-TEER, including both FDA-approved and investigational devices, was associated with favorable safety outcomes including significantly lower in-hospital mortality, reduced acute kidney injury, and fewer perioperative complications compared to surgical or conservative management; however, a mortality benefit at 1-year follow-up was observed in only a single study, and limited to patients with intermediate-stage disease receiving T-TEER compared to medical therapy. Collectively, these studies suggest TriClip provides symptomatic benefit in select patients with severe TR with a reduction in the rate of heart failure hospitalizations; the absence of long-term comparative data and reliance on primarily patient-reported outcomes underscore the need for additional longer-term follow-up and continued evidence development.

Tricuspid Valve Replacement with Evoque

Clinical Context and Therapy Purpose

The purpose of transcatheter tricuspid valve replacement (TTVR) with the EVOQUE system in individuals with severe primary or secondary tricuspid regurgitation (TR), despite optimal medical therapy and deemed appropriate candidates for valve replacement by a heart team, is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with symptomatic severe primary or secondary TR for whom tricuspid valve replacement is deemed appropriate by a heart team.

Interventions

The therapy being considered is Evoque. Evoque is a TTVR system designed to treat severe tricuspid regurgitation by fully replacing the native valve. Delivered via transfemoral venous access and guided by transesophageal echocardiography, the self-expanding valve is anchored in place using a unique atrial and ventricular anchoring mechanism that engages the native leaflets and annulus. The device aims to eliminate regurgitation by providing a new trileaflet valve that restores forward flow and valve competence.

Comparators

Comparators of interest are guideline-directed medical therapy and surgical tricuspid valve replacement. Surgical replacement is generally performed via open-heart surgery and is reserved for patients with severe symptomatic tricuspid regurgitation who are appropriate surgical candidates. The decision to pursue surgery is influenced by the severity of valve dysfunction, the presence of right heart failure, prior cardiac surgeries, comorbidities, and overall surgical risk. Medical therapy, which includes diuretics and management of underlying conditions, remains the mainstay for patients deemed inoperable or at high surgical risk but does not address the underlying structural valve abnormality.

Outcomes

The general outcomes of interest are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. A summary of outcome scales and classifications relevant to the reviewed evidence base for tricuspid regurgitation is presented in Table 1.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

The TRISCEND II trial represents the first pivotal randomized controlled trial evaluating transcatheter TTVR using the EVOQUE system in patients with severe symptomatic TR.[28,] Conducted across 45 centers in the United States and Germany between May 2021 and April 2023, the study enrolled 400 patients in a 2:1 ratio to receive either TTVR with the EVOQUE device plus medical therapy (n=267) or medical therapy alone (n=133). Participants had a mean age of 79.2 years, 73% were classified as New York Heart Association (NYHA) functional class III or IV, and 54% had chronic kidney disease (see Table 9). TR was torrential or massive in 53% of patients, and the mean EuroSCORE II was 5.4%. The predominant mechanism of TR was secondary (74.1%), followed by primary and mixed causes.

The primary endpoint was a hierarchical composite outcome evaluated at 1 year, including all-cause mortality, right ventricular assist device implantation or transplantation, postindex tricuspid intervention, hospitalization for heart failure (HFH), and improvements in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score, NYHA functional class, and 6-minute walk distance (6MWD). A win ratio method was used for analysis, comparing all possible patient pairs between groups. The primary outcome significantly favored the valve replacement group, with a win ratio of 2.02 (95% CI, 1.56 to 2.62; p<.001). Patients in the EVOQUE group had greater clinical benefit across most individual components, including a higher proportion achieving ≥ 10-point improvement in KCCQ (66.4% vs. 36.5%), NYHA class improvement (78.9% vs. 24.0%), and ≥ 30-meter increase in 6-minute walk distance (47.6% vs. 31.8%) (see Table 10). Although the rates of death (12.6% vs. 15.2%) and HFH (20.9% vs. 26.1%) were numerically lower in the valve replacement group, the study was not powered to detect significant differences in these endpoints individually. TR reduction to mild or less was achieved in 95.3% of patients in the EVOQUE arm at 1 year, compared to only 2.3% in controls. Severe bleeding occurred in 15.4% of valve-treated patients compared to 5.3% in the control group (p=.003), and 17.4% of treated patients required new unplanned permanent pacemakers, compared to 2.3% of controls (p<.001). Reintervention of the tricuspid valve occurred in 3.2% of patients in the TTVR group and 0.6% in the medical therapy group; however, specific details regarding the type of reintervention performed were not reported. Limitations for the trial are summarized in Tables 10 and 11 and consisted of the presence of crossover in the control group, higher attrition in the control arm, and reliance on hierarchical composite outcomes, which were driven by subjective patient-reported metrics (see Table 10 and 11).

Table 9. Summary of Key Evoque RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
Hahn et al (2025)[28,]; TRISCEND II	US, EU	45	2021-2023	Symptomatic severe tricuspid regurgitation Mean age: 79 yrs NYHA Class III or IV: 71.6% Primary TR: 14% Secondary TR: 73% Torrential TR: 32%	Valve Replacement with Evoque + medical therapy (n=259)	Medical therapy alone (n=133)

NYHA: New York Heart Association class; TR: tricuspid regurgitation. RCT: randomized controlled trial.

Table 10. Summary of Key Evoque RCT Results

Study	Hierarchical Win Ratio at 1 yr[1]	KCCQ, % Δ ≥ 10 points at 1 yr	NYHA, % Δ ≥ 1 class at 1 yr	TR (no greater than moderate) at 1 yr	6MWT, Δ ≥ 30 meters at 1 yr	Adverse Events at 1 yr
Hahn et al (2025)[28].; TRISCEND II	392	307	309	299	273	392
Evoque + medical therapy (n=259)	21397	66.4%	78.9%	99.1%	47.6%	All-cause Mortality: 11.6% CV Mortality: 8.5% Severe bleeding: 15.4% Tricuspid valve re-intervention: 0.8% Arrhythmia and conduction disorder: 17.8% New unplanned pacemaker or cardiac implantable electronic device: 17.4%
Medical therapy alone (n=133)	10591	36.5%	24%	16.1%	31.8%	All-cause Mortality: 10.5% CV Mortality: 7.5% Severe bleeding: 5.3% Tricuspid valve re-intervention: 3% Arrhythmia and conduction disorder: 2.3% New unplanned pacemaker or cardiac implantable electronic device: 2.3%
Win Ratio (95% CI; p-value) or % difference	2.02 (1.56 to 2.62; p<.001)	29.9%	54.9%	83%	15.8%	All-cause Mortality: p=.87 CV Mortality: p=.85 Severe bleeding: p=.003 Tricuspid valve re-intervention: p=.19 Arrhythmia and conduction disorder: p<.001 New pacemaker or cardiac implantable electronic device: p<.001

6MWT: 6 minute walk test; CI: confidence interval; CV: cardiovascular; KCCQ: Kansas City Cardiomyopathy Questionnaire; NYHA: New York Heart Association; TR: tricuspid regurgitation.

Table 11. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Hahn et al (2025)[28].; TRISCEND II			5. Crossover allowed at 1 year follow-		2. 1 year follow-up only

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
			up; may influence ongoing trial time to event outcomes		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 12. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Hahn et al (2025)[28].; TRISCEND II	5. 2:1 patient allocation coupled with loss to follow-up in the control group may impact confidence in control estimates	1. Participants or study staff not blinded; 2. Outcome assessors not blinded		1. High rate of missing data for some outcome measures		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

The TRISCEND study was a prospective, multicenter, single-arm investigation designed to evaluate the safety and performance of the EVOQUE transfemoral tricuspid valve replacement system in patients with symptomatic, ≥ moderate TR who remained symptomatic despite optimal medical therapy.[29.] The study was conducted at 20 centers across North America and Europe and enrolled 176 TR patients. Patients in TRISCEND were predominantly elderly (mean age 78.7 ± 7.3 years) and female (71%), with a high burden of comorbidities (see Table 13). Notably, 75.4% were in NYHA functional class III or IV, and 88% had severe or greater TR at baseline. The mean EuroSCORE II was 5.1%, and Society of Thoracic Surgeons (STS) scores for mitral valve repair and replacement were 7.4% and 10.0%, respectively, highlighting the elevated surgical risk of this population. The study's primary performance endpoints included procedural success (defined as successful device deployment with

no significant paravalvular leak) and clinical success (defined as procedural success without major adverse events at 30 days). Procedural success was achieved in 93.0%, and device success in 94.4% of patients. At one year, TR was reduced to mild or less in 97.6% of patients (p<.001), with 69.0% achieving none or trace TR (see Table 14). Functionally, the procedure led to marked improvement in NYHA class, with 93.3% of patients in class I or II at one year (compared to 25.8% at baseline, p<.001). The KCCQ score increased by 25.7 points, and the 6MWD improved by 56.2 meters, both statistically significant (p<.001). Physical and mental components of the Short-Form 36 (SF-36) survey also improved significantly. The study reported an all-cause mortality of 9.1% and HFH rate of 10.2% at 1 year. Compared to the 12 months before the procedure, there was a 74.9% relative reduction in HFH (p<.001). The composite major adverse event rate at 1 year was 30.2%, driven primarily by severe bleeding (25.5%), including life-threatening and fatal events. The rate of new pacemaker implantation among those without prior devices was 13.3%, all occurring within the first 9 days after the procedure, and these implants were not pre-planned but rather a response to post-procedure conduction disturbances.

Several additional case series evaluating TTVR with the EVOQUE system were identified, involving between 25 and 38 patients.[30,31,32,] Patients were elderly (mean age 76 to 77 years) and uniformly at high surgical risk with STS or EuroSCORE II scores ranging from 8.6% to 9.1%. Nearly all had severe secondary TR and were classified as NYHA class III or IV at baseline. Technical success was high (92 to 100%), and TR severity was significantly reduced, with 87% to 96% of patients having residual TR ≤ 2+ at 30 days to 1-year follow-up. Functional improvement was high, with 70% to 80% of patients improving to NYHA class I or II by 30 days to 1 year follow-up. Adverse events were infrequent but consisted of major bleeding that occurred in up to 12% and new pacemaker implantation in 4% to 8%. At 1 year, all-cause mortality ranged from 0% to 14%.

Table 13. Summary of Key Evoque Case Series Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
Kodali et al (2023)[29,]; TRISCEND	Canada, EU, US (20 sites)	Mean age (78.7 years) STS Score: 7.4% EuroSCORE II: 5.1% TR > Severe: 88% Secondary TR: 68.2% NYHA Class III or IV: 92%	Evoque plus Medical Managment (N=176)	1 year (n=149)

NYHA: New York Heart Association class; STS: Society of Thoracic Surgeons; TR: tricuspid regurgitation.

Table 14. Summary of Key Evoque Case Series Results

Study	Treatment	KCCQ, change from BL	NYHA class I or II	TR (no greater than moderate)	Mortality	HFH
Kodali et al (2023)[29,]; TRISCEND	Evoque plus Medical Managment (N=176)	1 yr: 25.7 (p<.001)	BL: 25.8% 1 yr: 93.3%	BL: 11.9% 1 yr: 97.6%	All cause, 1 yr: 9.1%	1 yr: 10.2%

BL: baseline; HFH: heart failure hospitalization; KCCQ: Kansas City Cardiomyopathy Questionnaire; NYHA: New York Heart Association class; TR: tricuspid regurgitation.

Section Summary: Tricuspid Valve Replacement with Evoque

The evidence for the use of the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in patients with symptomatic tricuspid regurgitation (TR) includes a single-arm feasibility study (TRISCEND), a pivotal randomized controlled trial (TRISCEND II), and several additional case series. The TRISCEND study demonstrated that the EVOQUE device could be safely implanted in a high-risk population, with high procedural success and significant improvements in TR severity, functional status, and quality of life measures at 1 year. However, the study lacked a control group and had a high rate of major adverse events, primarily due to severe bleeding and pacemaker implantation, limiting the strength of its conclusions regarding comparative effectiveness. The subsequent

TRISCEND II trial, a multicenter RCT, found that TTVR with EVOQUE significantly improved a hierarchical composite endpoint compared to medical therapy alone, with greater improvements in Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, New York Heart Association (NYHA) class, and 6-minute walk distance. Although the device group showed numerically lower rates of mortality and heart failure hospitalization, the trial was not powered to detect differences in these individual clinical outcomes. TR reduction to mild or less was achieved in over 95% of patients receiving the device versus 2.3% of controls. The EVOQUE group in TRISCEND II also experienced higher rates of severe bleeding and new unplanned pacemaker implantation, raising safety considerations. Limitations of the RCT include reliance on patient-reported outcomes within a hierarchical composite, differential attrition between groups, limited duration of follow-up, and control group crossover, which may bias interpretation of results. While these early results are promising, additional long-term data from comparative trials are needed to confirm the clinical durability and safety profile of EVOQUE relative to other surgical approaches.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology and American Heart Association

In 2020, the American College of Cardiology (ACC) and the American Heart Association (AHA) released updated guidelines on the management of valvular heart disease, including recommendations for tricuspid regurgitation. While the guidelines support surgical intervention for patients with severe tricuspid regurgitation, they do not include specific recommendations for transcatheter therapies in the treatment of tricuspid valve disease (see Table 15).[33,]

Table 15. Recommendations on Interventions for Tricuspid Regurgitation

Recommendation	COR	LOE
Medical Management		
In patients with signs and symptoms of right-sided HF attributable to severe TR (Stage C and D), diuretics can be useful.	2a (Moderate)	C-EO[3]
In patients with signs and symptoms of right-sided HF attributable to severe secondary TR (Stages C and D), therapies to treat the primary cause of HF (e.g., pulmonary vasodilators to reduce elevated pulmonary artery pressures, GDMT for HF with reduced LVEF, or rhythm control of AF) can be useful.	2a (Moderate)	C-EO[3]
Surgical Intervention		
In patients with severe TR (Stages C and D) undergoing left-sided valve surgery, tricuspid valve surgery is recommended.	1 (Strong)	B-NR[1]
In patients with progressive TR (Stage B) undergoing left-sided valve surgery, tricuspid valve surgery can be beneficial in the context of either 1) tricuspid annular dilation (tricuspid annulus end diastolic diameter >4.0 cm) or 2) prior signs and symptoms of right-sided HF.	2a (Moderate)	B-NR[1]
In patients with signs and symptoms of right-sided HF and severe primary TR (Stage D), isolated tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations.	2a (Moderate)	B-NR[1]
In patients with signs and symptoms of right-sided HF and severe isolated secondary TR attributable to annular dilation (in the absence of pulmonary hypertension or left-sided disease) who are poorly responsive to medical therapy (Stage D), isolated tricuspid valve surgery can be beneficial to reduce symptoms and recurrent hospitalizations.	2a (Moderate)	B-NR[1]

Recommendation	COR	LOE
In asymptomatic patients with severe primary TR (Stage C) and progressive RV dilation or systolic dysfunction, isolated tricuspid valve surgery may be considered.	2b (Weak)	C-LD[2]
In patients with signs and symptoms of right-sided HF and severe TR (Stage D) who have undergone previous left-sided valve surgery, reoperation with isolated tricuspid valve surgery may be considered in the absence of severe pulmonary hypertension or severe RV systolic dysfunction.	2b (Weak)	B-NR[1]

Source: Adatped from Otto et al (2020).[33,]
[1]Moderate, nonrandomized; [2]Limited data; [3]Expert opinion, not based on randomized trials or observational studies.
AF: atrial fibrillation; COR: class of recommendation; GDMT: guideline-directed medical therapy; HF: heart failure; LOE: level of evidence; LVEF: left ventricular ejection fraction; TR: tricuspid regurgitation.

The European Society of Cardiology and the European Association for Cardio-Thoracic Surgery

The European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) issued guidelines on the management of valvular heart disease in 2022.[34,]

- "TTVI (transcatheter tricuspid valve interventions) are under clinical development. Early registry and study data demonstrated the feasibility to reduce tricuspid regurgitation using various systems, enabling either leaflet approximation, direct annuloplasty, or valve replacement, with subsequent symptomatic and haemodynamic improvement."
- "TTVI may be considered by the Heart Team at experienced Heart Valve Centres in symptomatic, inoperable, anatomically eligible patients in whom symptomatic or prognostic improvement can be expected."
- "Transcatheter treatment of symptomatic secondary severe tricuspid regurgitation maybe considered in inoperable patients at a Heart Valve Centre with expertise in the treatment of tricuspid valve disease." Class IIb, Level of Evidence: C

National Institute for Health and Care Excellence

The NICE guideline on transcatheter tricuspid valve leaflet repair for tricuspid regurgitation (2022) makes the following recommendations related to transcatheter tricuspid valve repair:[35,]

- "1.1 - For people with severe and symptomatic tricuspid regurgitation, evidence on the efficacy of transcatheter tricuspid valve leaflet repair is limited in quantity and quality. Evidence on its safety shows there are serious but well-recognised complications. Therefore, for these people, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research."
- "1.2 - For people with mild or moderate tricuspid regurgitation, evidence on the safety and efficacy of transcatheter tricuspid valve leaflet repair is inadequate in quantity and quality. Therefore, for these people, this procedure should only be used in the context of research."
- "1.5 - The procedure should only be done in specialised centres with experience of the interventional management of tricuspid regurgitation. There should be immediate, onsite access to cardiac and vascular surgery."
- "1.6 - Further research should include details of patient selection, including the type and severity of tricuspid regurgitation."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services issued a National Coverage Decision for the use of transcatheter tricuspid valve replacement 2025.

A Proposed Decision Memo for Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation has been proposed with an expected review date of July 2025.

The Centers for Medicare & Medicaid Services determined that it would cover transcatheter tricuspid valve replacement under Coverage with Evidence Development for the treatment of symptomatic TR despite optimal medical therapy who are considered appropriate by a heart care team when all of the following conditions are met:

- "Despite optimal medical therapy (OMT), patients must have symptomatic TR with tricuspid valve replacement being considered as appropriate by a heart team."
- "The patient (preoperatively and postoperatively) is under the care of a heart team, which includes, at minimum, the following:
    -
        - Cardiac surgeon;
        - Interventional cardiologist;
        - Cardiologist with training and experience in heart failure management;
        - Electrophysiologist;
        - Multi-modality imaging specialists; and
        - Interventional echocardiographer.
    - All of the specialists listed above must have experience in the care and treatment of tricuspid regurgitation. "
- "The TTVR items and services are furnished in the context of a CMS-approved CED study."

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 15.

Table 15. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03904147	Clinical Trial to Evaluate Cardiovascular Outcomes In Patients Treated With the Tricuspid Valve Repair System Pivotal	572	Apr 2029
NCT04221490	Edwards EVOQUE Tricuspid Valve Replacement: Investigation of Safety and Clinical Efficacy After Replacement of Tricuspid Valve With Transcatheter Device	228	Jan 2029
NCT04433065	The Early Feasibility Study of the Transcatheter Tricuspid Valve Replacement System Transfemoral System	150	Jul 2031
NCT04482062	Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Pivotal Clinical Investigation of Safety and Clinical Efficacy Using a Novel Device	1070	Dec 2029
NCT04483089	An Observational Real-world Study Evaluating Severe Tricuspid Regurgitation Patients Treated with the Abbott TriClip™ Device	511	Jan 2028
NCT04570163	Berlin Registry of Right Heart Interventions	200	Dec 2025
NCT04634266	TRICuspid Intervention in Heart Failure Trial (TRICI-HF-DZHK24)	360	Mar 2027
NCT04735003	TRans-catheter Interventions for triCuspid Valve Insufficiency: the iTalian Multicentre Study	200	Jan 2027
NCT05179616	Pforzheim Tricuspid Valve Registry: A Real-world Observational Trial Evaluating Outcomes in Patients Treated With the Abbott TriClip™ Device in Helios Klinikum Pforzheim	200	Nov 2026
NCT05436028	TRIal to Evaluate TraNsvenous TrIcuspid Valve ReplacemenT With LuX-Valve Plus System in Patients With Severe or Greater Tricuspid Regurgitation -- SafetY and Clinical Performance	281	Oct 2029
NCT05486832	Safety and Performance of the Cardiovalve TR Replacement System for Tricuspid Regurgitation	100	Dec 2026
NCT05628779	Evaluation of the Safety, Efficacy and Cost-effectiveness of Transcatheter Tricuspid Valve Repair in Patients With Severe Tricuspid Regurgitation in the Netherlands.	150	Nov 2027
NCT05760989	Edwards EWJ-202 Transcatheter Tricuspid Valve Replacement System: Investigation of Safety and Clinical Efficacy Using a Novel Device in Patients With at Least Severe Tricuspid Regurgitation in JAPAN	45	Sep 2029

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT06307262	European Registry of Transcatheter Repair for Tricuspid Regurgitation (EuroTR)	3000	Dec 2030
NCT06033274	Global Multicenter Registry on Transcatheter TRIcuspid Valve RePLACEment: the TRIPLACE Registry	200	Aug 2027
NCT06569602	Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Real World European Investigation of Safety and Clinical Efficacy Using a Novel Device	500	Sep 2033
NCT06581471	The TRICURE EU PIVOTAL TRiCares Topaz Transcatheter TRICUspid Heart Valve REplacement System EUropean PIVOTAL Study	80	Dec 2030
NCT06611579	A Clinical Study of the InQB8 Transcatheter Tricuspid Valve Replacement System	50	Oct 2029
NCT06833476	Transcatheter Tricuspid Valve Replacement (TTVR) in Patients With Severe TR ONgoing Evidence Generation (STRONG) Under Coverage With Evidence Development (CED)	2044	Dec 2032

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

Appendix 1

Appendix Table 1. 5 Grade Scale for Tricuspid Regurgitation Severity[36,]

	Trace/mild	Moderate	Severe (Severe 3)	Massive (Severe 4)	Torrential (Severe 5)
Vena contracta (biplane, mm)	<3	3-6.9	7-13	14-20	≥21
PISA radius (mm)	<6	6-9	>9	>9	>9
EROA (mm^2)	<20	20-39	40-59	60-79	≥80
Regurgitant volume (mL)	<15	15-44	40-59	60-74	≥75
3D VCA or quantitative EROA (mm^2)			75-94	95-114	≥115
IVC diameter (cm)	<2	2.1-2.5	>2.5	>2.5	>2.5
Hepatic flow	Systolic dominant	Systolic blunt	Systolic reversal	Systolic reversal	Systolic reversal

3D VCA: three-dimensional vena contracta area; EROA: effective regurgitant oriface area; IVC: inferior vena cava; PISA: proximal isovelocity surface area.

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Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history, if applicable
  - Reason for procedure/test/device, when applicable
  - Pertinent past procedural and surgical history
  - Past and present diagnostic testing and results
  - Prior conservative treatments, duration, and response
  - Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (i.e., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management), when applicable

Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Procedure report(s)

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	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
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/01/2025	New policy.

Definitions of Decision Determinations

Healthcare Services: For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

Medically Necessary: Healthcare Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield of California, are: (a) consistent with Blue Shield of California medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the member; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the member's illness, injury, or disease.

Investigational or Experimental: Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

A. The technology must have final approval from the appropriate government regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug

Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
- Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
- The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
- The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
- The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
- When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER Blue font: Verbiage Changes/Additions
New Policy Policy Statement: N/A	Transcatheter Tricuspid Valve Repair or Replacement 2.02.34 Policy Statement: I. Transcatheter tricuspid edge to edge repair (T-TEER) with a device approved by the U.S. Food and Drug Administration (FDA) for use in tricuspid valve repair may be considered medically necessary for individuals with severe tricuspid regurgitation (TR) despite the use of maximally tolerated guideline-directed medical therapy who are considered at intermediate or high risk for open surgery as assessed by a heart team (see Policy Guidelines section). II. Transcatheter tricuspid valve replacement (TTVR) with a device approved by the U.S. FDA may be considered medically necessary for individuals with severe TR despite the use of maximally tolerated guideline-directed medical therapy who are TTVR candidates as identified by a heart team (see Policy Guidelines section). III. T-TEER and TTVR are considered investigational in all other situations.