

Transcatheter Tricuspid Valve Repair or Replacement

Policy # 00931

Original Effective Date: 09/01/2025

Current Effective Date: 09/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Transcatheter Aortic-Valve Implantation for Aortic Stenosis is addressed separately in medical policy 00406.

Note: Transcatheter Mitral Valve Repair or Replacement is addressed separately in medical policy 00494.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers transcatheter tricuspid edge to edge repair (T-TEER) and transcatheter tricuspid valve replacement (TTVR) to be **investigational***.

Note: The Evoque^{TM†} Tricuspid Valve Replacement System (Edwards Lifesciences, Co.) and the TriClip^{TM†} G4 System (Abbott Medical) are currently the only FDA-approved devices for tricuspid valve replacement and repair.

Background/Overview

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 approximately 4% 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.

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Table 1.

5 Grade Scale for Tricuspid Regurgitation Severity

	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)	<30	30-44	45-59	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 orifice area; IVC: inferior vena cava; PISA: proximal isovelocity surface area.

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 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. 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).

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.

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

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The Evoque^{TM‡} Tricuspid Valve Replacement System (Edwards Lifesciences, Co.) and the TriClip^{TM‡} G4 System (Abbott Medical) are currently the only FDA-approved devices for tricuspid valve replacement and repair. Several additional devices, the PASCAL^{TM‡} Transcatheter Valve Repair System, a transcatheter edge-to-edge repair device similar to TriClip, and the Cardioband^{TM‡} 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.

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.

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

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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.

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.

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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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, TriClipTM‡ (Abbott) and EVOQUETM‡ (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.

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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 1 meta-analysis, 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. Tricuspid regurgitation 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 (annualized HFH event rates of 0.19 vs 0.26 events/patient-year; $p=.02$). 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 (HR:0.73; 95% CI: 0.52-0.99; $P=0.03$). In a 2025 comparison study (Shimoda; using Medicare data) of T-TEER versus surgical tricuspid valve repair, there was no differences at 2 years in heart failure hospitalizations and tricuspid valve reinterventions were more frequent in the T-TEER group (subdistribution hazard ratio, 8.03 [95% CI, 2.87-22.48]). Authors concluded that further studies are necessary to refine indications, patient selections, and optimal timing for intervention with either treatment strategy. A 2025 meta-analysis reported reductions in all-cause mortality and heart failure hospitalization with T-TEER compared with medical management. However, the mortality effect was primarily attributable to observational studies and was not observed in pooled randomized controlled trial analyses. Interpretation is additionally limited by inclusion of non-FDA-approved devices and heterogeneity in comparator medical management. Therefore the findings do not resolve uncertainty regarding the effect of T-TEER on survival and major clinical outcomes.

Collectively, these studies suggest that TriClip provides symptomatic benefit in select patients with severe tricuspid regurgitation. There is insufficient and inconsistent evidence to demonstrate improvements in survival benefit, heart failure hospitalizations, or freedom from tricuspid valve

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reinterventions. The absence of long-term comparative data, lack of sham control, and reliance on primarily patient-reported outcomes underscore the need for additional longer-term follow-up and continued evidence development (as required by the FDA). Patient selection criteria (including type and severity of tricuspid regurgitation) need to be clearly defined in additional studies to identify the most appropriate candidates for this procedure. The evidence is insufficient 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, randomly assigned 400 patients with severe symptomatic tricuspid regurgitation in a 2:1 ratio to either transcatheter tricuspid valve replacement and medical therapy (valve-replacement group) or medical therapy alone (control group). The trial 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 (15.4% vs 5.3%) and new unplanned pacemaker implantation (17.4% vs 2.3%), raising safety considerations. Limitations of the RCT include reliance on patient-reported outcomes within a hierarchical composite, lack of sham control, differential attrition between groups, limited duration of follow-up, and control group crossover, which may bias interpretation of results. Although post-approval registry data demonstrated procedural feasibility and symptomatic improvement, registry studies lack randomized comparators and are insufficient to establish improvement in survival, heart failure hospitalization, or long-term valve durability.

Additional long-term data from comparative trials are needed to confirm impact on survival, heart failure hospitalization, and the clinical durability and safety profile of EVOQUE relative to other surgical approaches (as required by the FDA). Patient selection criteria (including type and severity of tricuspid regurgitation) need to be clearly defined in additional studies to identify the most appropriate candidates for this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

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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 2).

Table 2. 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

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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: Adapted from Otto et al (2020).¹

¹Moderate, nonrandomized; ²Limited data; ³Expert 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

In 2025, the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) issued updated guidelines on the management of valvular heart disease. For tricuspid regurgitation, the guidelines emphasize early referral and structured evaluation of right ventricular function and pulmonary pressures (Class I) and incorporate transcatheter therapies as formal recommendations supported by randomized evidence.

- "Careful evaluation of TR aetiology, stage of the disease (i.e. degree of TR severity, RV and LV dysfunction, and PH), patient operative risk, and likelihood of recovery by a multidisciplinary Heart Team is recommended in patients with severe TR prior to intervention." Class I, Level of Evidence: C
- "Transcatheter TV treatment should be considered to improve quality of life and RV remodelling in high-risk patients with symptomatic severe TR despite optimal medical therapy in the absence of severe RV dysfunction or pre-capillary PH." Class IIa, Level of Evidence: A.
- For patients undergoing left-sided valve surgery, concomitant TV repair is recommended in those with severe primary or secondary TR (Class I, LOE B); should be considered in those with moderate primary or secondary TR to avoid progression of TR and RV remodelling (Class IIa, LOE B); and may be considered in selected patients with mild secondary TR and tricuspid annulus dilatation (≥ 40 mm or > 21 mm/m²) (Class IIb, LOE B).
- "Transcatheter TV procedures should be performed at an experienced Heart Valve Centre with expertise in the treatment of TV disease."

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:

- "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.

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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 (effective March 19, 2025).

A subsequent National Coverage Determination (NCD 20.38) for Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation was finalized on July 2, 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.*Note: 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."

The Centers for Medicare & Medicaid Services determined that it would cover transcatheter edge-to-edge repair for tricuspid valve regurgitation under Coverage with Evidence Development (CED)

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for the treatment of symptomatic TR despite optimal medical therapy for individuals who are considered appropriate by a heart team when all of the following conditions are met:

- "Despite optimal medical therapy (OMT), patients must have symptomatic severe tricuspid regurgitation with tricuspid valve repair 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; and
 - Interventional echocardiographer.
 - All of the specialists listed above must have experience in the care and treatment of tricuspid regurgitation."
- "The T-TEER 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 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
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	864	Jun 2030
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 2035

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NCT04634266	TRICuspid Intervention in Heart Failure Trial (TRICI-HF-DZHK24)	360	Dec 2026
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
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
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	800	Aug 2026
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

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Unpublished			
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	161	Nov 2024 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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08/07/2025 Medical Policy Committee review

08/13/2025 Medical Policy Implementation Committee approval. New policy.

08/06/2026 Medical Policy Committee review

08/12/2026 Medical Policy Implementation Committee review

08/20/2026 Medical Quality Management Committee approval. *Note added after the investigational statement: The Evoque^{TM†} Tricuspid Valve Replacement System (Edwards Lifesciences, Co.) and the TriClip^{TM†} G4 System (Abbott Medical) are currently the only FDA-approved devices for tricuspid valve replacement and repair. Coverage eligibility unchanged.*

10/01/2026 Coding update

Next Scheduled Review Date: 08/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)[‡], copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0569T, 0570T, 0646T Add code effective 10/01/2026: 0545T
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from

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carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.