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MEDICAL POLICY – 2.02.518

Transcatheter Tricuspid Valve Repair or Replacement

BCBSA Ref. Policy:	2.02.34	
Effective Date:	**Jan. 2, 2026***	RELATED MEDICAL POLICIES:
Last Revised:	Sep. 9, 2025	2.02.30 Transcatheter Mitral Valve Repair or Replacement
Replaces:	N/A	7.01.132 Transcatheter Aortic Valve Implantation for Aortic Stenosis

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | APPENDIX | HISTORY

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Introduction

Tricuspid valve regurgitation (TR) is a condition in which blood flows backward from the lower chamber to the upper chamber on the right side of the heart. In severe cases, this backward flow can lead to symptoms of right-sided heart failure, such as swelling in the legs or abdomen, an enlarged liver, fatigue, and reduced ability to carry out daily activities. For individuals who do not respond to medication or are not good candidates for open-heart surgery, less invasive treatments may be performed in a cardiac catheterization lab. These options include transcatheter tricuspid edge-to-edge repair (T-TEER), which uses a device to bring the valve flaps closer together to reduce leakage, and transcatheter tricuspid valve replacement (TTVR), in which the damaged valve is replaced with a prosthetic one. Both procedures aim to restore normal blood flow through the right side of the heart and relieve symptoms of severe TR. Both T-TEER and TTVR are considered investigational. This means more research is needed to determine how effective and safe these procedures are for treating severe tricuspid regurgitation.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
T-TEER or TTVR	**Transcatheter tricuspid edge-to-edge repair (T-TEER) and transcatheter tricuspid valve replacement (TTVR) are considered investigational for all indications.**

Coding

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

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

High risk for open heart surgery: 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 as defined by the FDA.

Intermediate risk for open heart surgery: STS predicted risk of mortality between 3% and 7% as defined by the FDA.

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

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

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, electrophysiologist, multi-modality imaging specialists, and interventional echocardiographer.

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 individuals 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. Individuals must be able to tolerate at least one antiplatelet medication AND one anticoagulant medication.

Evidence Review

Description

Transcatheter tricuspid valve repair or replacement is an emerging alternative to surgical therapy for individuals 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 individuals with severe symptomatic TR who are not suitable candidates for surgery and continue to experience symptoms despite optimized medical therapy.

Background

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 individuals 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 individuals 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 individuals 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).

Summary of Evidence

The evidence for the use of TriClip in individuals 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 individuals with intermediate-stage disease receiving T-TEER compared to medical therapy. Collectively, these studies suggest TriClip provides symptomatic benefit in select individuals 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. However, safety and effectiveness for routine clinical application have not been established for this procedure. Therefore, the Plan considers this procedure investigational for all indications.

The evidence for the use of the EVOQUE transcatheter tricuspid valve replacement (TTVR) system in individuals 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 individuals 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. However, safety and effectiveness for routine clinical application have not been established for this procedure. Therefore, the Plan considers this procedure investigational for all indications.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in **Table 1**.

Table 1. 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

NCT No.	Trial Name	Planned Enrollment	Completion Date
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
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.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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 individuals with severe tricuspid regurgitation, they do not include specific recommendations for transcatheter therapies in the treatment of tricuspid valve disease (see **Table 2**).[33]

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]

Recommendation	COR	LOE
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]
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).[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 may be 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."

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."

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 individuals or all treated in the first 2 years, with a detailed subgroup of 1,000 individuals 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 individuals 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 individuals 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 individuals (or all individuals 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 individuals from each racial/ethnic group, including Black, Asian, Native American, Pacific Islander, and Hispanic/Latino individuals.

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Appendix

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 (mm2)	<20	20-39	40-59	60-79	≥80
Regurgitant volume (mL)	<15	15-44	40-59	60-74	≥75
3D VCA or quantitative EROA (mm2)			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.

History

Date	Comments
10/01/25	New policy, approved September 9, 2025, effective for dates of service on or after January 2, 2026, following 90-day provider notification. Add to Cardiology section. Policy updated with literature review through March 18, 2025. T-TEER and TTVR are considered investigational for all indications.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member

benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.