Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

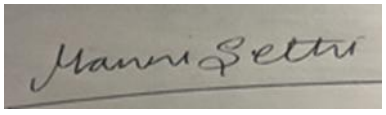
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date:1/1/2026
Policy Number: ccp.1551	Effective Date:12/1/2025 Revision Date:
Policy Name: Transcatheter Therapy for Severe Tricuspid Insufficiency	

Type of Submission:

☒ New Policy	☒ Prior Authorization Policy
☐ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Transcatheter Therapy for Severe Tricuspid Insufficiency

Clinical Policy ID: CCP.1551

Recent review date: 11/1/2025

Next review date: 3/1/2027

Policy contains: Evoque; heart failure; TriClip; tricuspid insufficiency; tricuspid valve repair; tricuspid valve replacement.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Transcatheter edge-to-edge repair and transcatheter tricuspid valve replacement procedures for severe tricuspid insufficiency (also called tricuspid regurgitation) are investigational/not clinically proven and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Guideline-directed medical therapy
- Surgical tricuspid valve repair
- Surgical tricuspid valve replacement

Background

Tricuspid insufficiency (or regurgitation) results from structural abnormalities of the tricuspid valve complex that cause incomplete valve closure and retrograde flow of blood from the right ventricle into the right atrium during

systole. In U.S. adults, the incidence of tricuspid regurgitation ranges from 5% to 20%. Tricuspid regurgitation-related morbidity and mortality increase with severity (Mulla, 2024).

Tricuspid regurgitation is categorized as either primary, caused by intrinsic abnormalities in the tricuspid valve apparatus, or secondary, caused by right atrial or ventricular dilatation. A third category, tricuspid regurgitation related to a cardiac procedure such as endomyocardial biopsy or implantable electronic device, can develop if the device interferes with the tricuspid valve leaflets or subvalvular apparatus, or if right ventricular pacing leads to right ventricular remodeling (O'Gara, 2025).

A combination of structural, qualitative, semiquantitative, and quantitative measures using echocardiography is used to assess valvular morphology, severity of tricuspid regurgitation, and adjunctive cardiac features. Cardiac magnetic resonance and computed tomography may further define complex tissue structures. The severity of tricuspid regurgitation is commonly graded as mild (1+), moderate (2+), or severe (3+). More recently, severe disease may be further graded as massive or torrential. Guideline-directed diagnosis of severe tricuspid regurgitation is based on assessment of regurgitant jet area with vena contracta and presence of hepatic vein reverse flow. Severe (3+) classification is defined by a vena contracta diameter of at least 7 millimeters, effective regurgitant orifice area of at least 40 square millimeters, and/or a regurgitant volume of at least 45 millilters per beat (Ambrosino, 2024).

Patients with severe tricuspid regurgitation usually present with signs or symptoms of right-sided heart failure. The prognostic impact of a tricuspid regurgitation diagnosis is well recognized, but the effect of its correction is less so. Treatment options are limited to guideline-directed medical therapy for symptom relief and surgery. Surgical intervention for isolated tricuspid regurgitation is relatively uncommon in the United States due to a perceived high in-hospital mortality rate of up to 10%, despite stringent selection criteria. Instead, surgery is performed typically for those who have another primary indication for surgery, such as concomitant mitral or aortic valvular disease, or to prevent later development of severe tricuspid regurgitation in patients with progressive tricuspid disease. Earlier referral and more effective techniques may improve patient outcomes (Ambrosino, 2024).

Transcatheter tricuspid valve interventions

Minimally invasive, transcatheter tricuspid valve interventions have emerged as potential options for tricuspid valve repair and replacement. The options for transcatheter repair are leaflet coaptation devices (tricuspid valve edge-to-edge repair) and annuloplasty. Transcatheter replacement options include orthotopic replacement of the tricuspid valve and heterotopic caval valve implantation (Ambrosino, 2024).

As of this writing, two transcatheter options have received regulatory approval for clinical use in the United States. The TriClip G4 transcatheter tricuspid valve repair system (Abbott Medical, St. Paul, Minnesota) is delivered via a transfemoral venous approach under transesophageal echocardiographic guidance. It uses a specialized clip to grasp and join together the edges of the leaking valve leaflets, which creates a stable double orifice. This 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. Regulatory approval is based on the results of the TRILUMINATE Pivotal Trial (Kar, 2025; ClinicalTrials.gov identifier NCT03904147; U.S. Food and Drug Administration, 2024b).

The Edwards Evoque Tricuspid Valve Replacement System (Edwards Lifesciences LLC, Irvine, California) is made from bovine pericardial tissue, uses a transfemoral venous approach, and comes in three sizes. It replaces the native tricuspid heart valve without concomitant removal of the failed native valve. This device is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal

medical therapy, in whom tricuspid valve replacement is deemed appropriate by a heart team. Regulatory approval was based on the safety and effectiveness results from the TRISCEND II pivotal trial (ClinicalTrials.gov identifier NCT04482062, U.S. Food and Drug Administration, 2024a).

Findings

Isolated severe tricuspid regurgitation is associated with high surgical risk and long-term mortality risk, and advances in medical and surgical management have not lowered mortality rates (Suc, 2025). Transcatheter options are recent additions that are safe and improve the severity of tricuspid regurgitation and health status in patients at high or prohibitive surgical risk, but evidence is lacking on mortality and heart failure hospitalization rates, efficacy in patients with mild or moderate tricuspid regurgitation, and long-term outcomes (Donal, 2025; Hahn, 2025; Sorajja, 2023). Current guidelines acknowledge the limited available evidence and provide mixed recommendations for clinical use outside of research protocols.

Guidelines

The current American College of Cardiology guideline on valvular heart disease acknowledges a growing interest in catheter-based therapies for tricuspid regurgitation but issued no recommendation (Otto, 2020).

In 2025, an American College of Cardiology writing committee summarized the most important developments for patients with severe tricuspid regurgitation, with emphasis on those with secondary tricuspid regurgitation in the chronic setting. Transcatheter interventions are in the early stages of new device development and testing in clinical trials. Most current trial data reflect a patient population with high or prohibitive surgical risk. Ongoing studies are comparing the effectiveness of transcatheter options to optimal medical therapy; comparisons to isolated tricuspid valve surgery or to other transcatheter options have not been conducted. The writing committee recommends counseling patients on expected benefits and risks with both surgical and available transcatheter interventions within a multidisciplinary team consensus and shared decision-making (O'Gara, 2025).

The European Society of Cardiology and the European Association for Cardio-Thoracic Surgery joint guideline on the management of valvular heart disease addressed all transcatheter tricuspid valve options available in the European Union, including TriClip and Evoque. The guideline states transcatheter tricuspid valve treatment should be considered to improve quality of life and right ventricular remodeling in high-risk patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, and in the absence of severe right ventricular dysfunction or pre-capillary pulmonary hypertension (Class IIa recommendation; Level of evidence A based on data derived from randomized controlled trials or meta-analyses) (Praz, 2025).

The National Institute for Health and Care Excellence (2022) states transcatheter tricuspid valve leaflet repair should only be used with special arrangements for clinical governance, consent, and audit or research. For individuals with severe and symptomatic tricuspid regurgitation, evidence on efficacy is limited in quantity and quality, and there are serious but well-recognized complications. For individuals with mild or moderate tricuspid regurgitation, evidence on the safety and efficacy is of inadequate quantity and quality.

Evidence review

Data from three randomized controlled trials demonstrate the safety and efficacy of transcatheter tricuspid valve repair (TriClip) and replacement (Evoque) procedures in reducing the severity of tricuspid regurgitation in more than 80% of cases where anatomical suitability was confirmed. These results and improvement in health status were sustained up to one year for Evoque and up to two years for TriClip. The effects of transcatheter interventions on rates of heart failure hospitalization and mortality may be realized with longer follow up, as evidence for TriClip suggests.

Transcatheter edge-to-edge repair is the most extensively studied transcatheter technique for severe tricuspid regurgitation. Compared to TriClip, Evoque is associated with more procedural complications but a lower rate of residual tricuspid regurgitation. It appears to be most suitable for patients who have anatomy that precludes repair, and it has the ability to treat a wider range of tricuspid regurgitation pathologies.

Transcatheter tricuspid valve edge-to-edge repair (TriClip)

The evidence for the TriClip procedure consists of results from the TRILUMINATE Pivotal trial carried out in the United States (n = 350; Jorde, 2024; Kar, 2025; Naik, 2025; Sorajja, 2023) and from the TRI.Fr randomized controlled trial in Europe (n = 300; Donal, 2025). Both trials compared the safety and efficacy of optimized medical therapy with and without TriClip for treating severe, symptomatic, isolated tricuspid regurgitation. Both trials reported outcomes at 12 months. TRILUMINATE also reported full two-year follow-up data (Kar, 2025) and three-year follow-up data from a cohort of TriClip recipients (Nickenig, 2024).

The main eligibility criteria for inclusion in both of these trials were New York Heart Association class II to IV heart failure; on guideline-directed medical therapy and stable for at least 30 days; free from other cardiovascular conditions requiring intervention; and considered intermediate-to-high risk for surgery. In general, participants with highly advanced disease (e.g., severe kidney failure, liver failure, advanced cardiorenal syndrome, or pulmonary artery systolic pressure > 60 millimeters of mercury) were excluded. The mean age of participants was 78 years, and a slight majority were women. Participants had significantly impaired quality of life at baseline, and a high proportion experienced heart failure hospitalizations in the previous year (Donal, 2025; Sorajja, 2023).

TriClip safety

Transcatheter tricuspid valve edge-to-edge repair using TriClip is a safe procedure in experienced hands. TriClip was successfully implanted in at least 97% of participants. TriClip was associated with low rates of periprocedural adverse events, which were comparable to the control arms. At 12 months, rates of major cardiovascular events, deaths, and hospitalizations were similar between study arms. Single-leaflet device attachments occurred in 5.2% in the TRI.Fr trial and 7.0% in the TRILUMINATE trial (Donal, 2025; Sorajja, 2023).

In the TRI.Fr trial, three recipients of TriClip required tricuspid valve surgery, five required a cardiac electronic rhythm device, and nine experienced a major bleed. These results did not differ significantly from the control group (Donal, 2025). In the TRILUMINATE trial, five TriClip recipients and five in the control group required a cardiac electronic rhythm device (Sorajja, 2023).

TriClip efficacy

The TRILUMINATE and TRI.Fr trials used composite clinical endpoints at 12 months as their primary outcome measures. The composite endpoints differed in composition but included elements of objective adverse cardiovascular event data and patient-reported outcome measures (Donal, 2025; Sorajja, 2023).

At year one, the results of the primary endpoint favored the TriClip arm, driven by the magnitude of improvement in patient-reported outcome measures, including quality of life, rather than by changes in the rates of cardiovascular hospitalization or cardiovascular death. Significantly more TriClip recipients experienced a reduction in the severity of tricuspid regurgitation, from severe or greater to moderate or less, than those on optimized medical therapy alone. These results suggest a correlation between quality-of-life improvement and reduction in tricuspid regurgitation up to one year following the procedure. The trials reached different conclusions regarding the impact of TriClip on the six-minute walk test distance (Donal, 2025; Sorajja, 2023).

A separate analysis of 98 participants with transvalvular cardiac implantable electronic devices at baseline found TriClip repair was safe and effective and did not affect device function up to one year (Naik, 2025). Jorde (2024) observed potential benefits for TriClip repair in improving end organ renal and liver function, but additional

research is needed to assess whether the statistically significant improvements are clinically meaningful and reduce mortality or heart failure hospitalization.

At year two, results of the TRILUMINATE trial showed sustained benefits of TriClip repair versus controls in terms of improved tricuspid regurgitation, health status, and comparable adverse event rates. Notably, 59% of the control participants crossed over to the TriClip group before the two-year follow-up. From year one to year two, the TriClip group showed a significantly greater reduction in the rate of heart failure hospitalization and freedom from all-cause mortality, tricuspid valve surgery, and tricuspid valve intervention compared with medical therapy. These findings were driven by the crossover of controls to the TriClip group, who were more symptomatic and had more severe tricuspid regurgitation, higher hospitalization rates, and worsened functional score than those who remained in the control group. Rates of all-cause mortality and tricuspid valve surgery remained similar between groups (Kar, 2025).

At year three, in a subset of 98 TRILUMINATE TriClip recipients, major adverse events included cardiovascular mortality (n = 18), myocardial infarction (n = 1), stroke (n = 4), and new onset of renal failure (n = 8). Benefits in reduced tricuspid regurgitation, favorable remodeling of the right heart, and improved heart failure symptoms were maintained. There was a 75% reduction in heart failure hospitalizations, from 0.56 events/patient-year in year one to 0.14 events/patient-year in year three ($P < .0001$). Those who achieved a reduction in tricuspid regurgitation from severe or greater to moderate or less at 30 days were less likely to experience heart failure hospitalization or death by year three compared with those who maintained severe or greater tricuspid regurgitation at 30 days (30.7% vs. 50.7%, hazard ratio = 0.48, 95% confidence interval 0.25 to 0.93, $P = .026$). Quality of life, measured by the Kansas City Cardiomyopathy Questionnaire score, initially improved in year one, but declined at year three, yet still maintained a 10-point improvement over baseline (Nickenig, 2024).

Transcatheter tricuspid valve replacement (Evoque)

The evidence for transcatheter tricuspid valve replacement using Evoque consists of results from the TRISCEND II pivotal randomized controlled trial (Arnold, 2025; Hahn, 2025). Eligibility criteria included participants at least 18 years of age with severe, massive, or torrential tricuspid regurgitation, who were eligible for valve replacement, and had either signs or symptoms of tricuspid regurgitation or a recent hospitalization for associated heart failure despite medical therapy. The vast majority of enrollees were white women with a mean age of 79 years. There was a high prevalence of hypertension, atrial fibrillation, left ventricular ejection fraction of more than 50%, and substantially impaired health status at baseline. Participants also had a high prevalence of renal insufficiency and history of bleeding (Hahn, 2025).

Participants were randomized to the valve-replacement group (n = 267) or medical therapy alone (n = 133). The hierarchical composite primary outcome was death from any cause, implantation of a right ventricular assist device or heart transplantation, subsequent tricuspid-valve intervention, heart failure hospitalization, an improvement of at least 10 points in the score on the Kansas City Cardiomyopathy Questionnaire overall summary, an improvement of at least one New York Heart Association functional class, and an improvement of at least 30 meters on the six-minute walk test distance. Investigators used the win ratio to analyze the composite endpoint, which prioritizes each element based on clinical importance in terms of the proportion of successful outcomes compared to unsuccessful ones (Hahn, 2025).

Evoque safety

Most adverse clinical events occurred peri-procedurally, driven primarily by severe bleeding (10.4% in the valve replacement group vs. 1.5% in controls, $P = .003$) and conduction disorders leading to new pacemaker implantation (15.8% vs. 0%, $P < .001$).

Evoque efficacy

At 30 days, the rates of death from any cause (P = .87) and death from cardiovascular causes (P = .85) were similar between groups. At year one, the primary composite endpoint favored valve replacement over medical therapy (win ratio 2.02, 95% confidence interval 1.56 to 2.62, P < .001), driven primarily by improvements in symptoms and quality of life. Echocardiographic outcomes favored the valve-replacement group, in whom tricuspid regurgitation was decreased to a mild degree or less in 95.2% compared with 2.3% of those in the control group. Authors observed improvements in right ventricular reverse remodeling and in markers of liver congestion (Hahn, 2025).

Adding transcatheter valve replacement resulted in substantial improvement in participants' symptoms, function, and quality of life over medical therapy alone. The magnitude of the health status benefit was directly related to the baseline severity of tricuspid regurgitation. Moderate benefits were evident 30 days after the procedure, continued to improve through the first six months, and were maintained through year one (Arnold, 2025).

References

On 9/24/2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "tricuspid valve insufficiency" (MeSH), "tricuspid valve insufficiency," "tricuspid valve regurgitation," "TriClip," and "EVOQUE." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

11/4/2025 initial review date and clinical policy effective date: 12/1/2025