

<b>Subject: Transcatheter Tricuspid Valve Replacement for Tricuspid Valve Disease</b>		<b>Original Effective Date: 6/17/2020</b>
<b>Policy Number: MCP-368</b>	<b>Revision Date(s):</b>	
<b>MCPC Approval Date: 6/17/2020</b>	<b>Review Date:</b>	

**DISCLAIMER**

*This Molina clinical policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina clinical policy document and provide the directive for all Medicare members.<sup>1</sup>*

**DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL** <sup>2 4 9 19 20 21</sup>

Tricuspid valve disease

Tricuspid valve disease is a condition in which the valve between the two right heart chambers (right ventricle and right atrium) does not function properly. Tricuspid valve disease often occurs with other heart valve problems. Tricuspid regurgitation (TR) is a commonly encountered manifestation of valvular heart disease. The majority of patients with TR have mild disease that is classified as nonpathological or a normal variant. These patients can remain asymptomatic for some time. Moderate-to-severe TR is usually considered pathological and is associated with poor prognosis. The prevalence of moderate-to-severe TR in the United States has been reported to be greater than 1.6 million. With severe TR, 1-year mortality increases and may reach greater than 36%. Surgical repair of TR is generally reserved for patients with advanced disease. These patients are often high-risk candidates for open surgical procedures, making the percutaneous or transcatheter minimally invasive approach attractive for this population. The current standard of care is open surgical valve replacement or repair surgery.

Transcatheter tricuspid valve replacement

Transcatheter heart valve replacement and repair are relatively new interventional procedures involving the insertion of an artificial heart valve or repair device using a catheter, rather than through open heart surgery, or surgical valve replacement (SAVR). The point of entry is typically either the femoral vein (antegrade) or

femoral artery (retrograde), or directly through the myocardium via the apical region of the heart. For valve replacement surgery, an expandable prosthetic heart valve is pressed onto a catheter and then deployed at the site of the diseased native valve. For valve repair, a small device is deployed by catheter to the valve where the faulty leaflets are clipped together to reduce regurgitation. The percutaneous transcatheter heart valve surgery procedure usually takes less time to perform and is less invasive than open heart surgery. Potential disadvantages of transcatheter heart valve surgery include a greater risk for valve migration, complications associated with catheter-based delivery, and uncertain valve device durability. Surgical repair of tricuspid valve is generally reserved for patients with advanced disease. These patients are often high-risk candidates for open surgical procedures, making the percutaneous or transcatheter minimally invasive approach attractive for this population. The development of devices specifically designed for percutaneous or transcatheter tricuspid valve replacement (TTVR) is currently at an early stage.

FDA: No transcatheter tricuspid valves are currently approved by the Food and Drug Administration for use in the United States. Multiple transcatheter devices intended for mitral, aortic, and pulmonic valve positions have been FDA approved. Use of any of these devices in the tricuspid position would be considered off-label. There are early studies evaluating use of several TTVR devices.<sup>19</sup>

#### RECOMMENDATION CLINICAL CRITERIA

Transcatheter tricuspid valve replacement for tricuspid valve disease is considered experimental, investigational and unproven due to insufficient published evidence to assess the safety and/or impact on health outcomes of transcatheter tricuspid valve replacement in patients with diseased tricuspid valves.

#### SUMMARY OF MEDICAL EVIDENCE<sup>2-15</sup>

At the current time there is a paucity of peer reviewed literature to evaluate the safety and/or impact on health outcomes of transcatheter tricuspid valve replacement in patients with diseased native tricuspid valves. Publications include mostly small case series. There is one large (n=312) prospective study and a small (n=30) single-arm, multicenter, prospective trial are outlined below.

Taramasso M et al., (2019) reported on a large, prospective international registry was developed to evaluate the initial clinical applications of transcatheter tricuspid valve intervention (TTVI) with different devices. TTVI for native tricuspid valve dysfunction has been emerging during the last few years as an alternative therapeutic option to serve a large high-risk population of patients with severe symptomatic tricuspid regurgitation (TR). The TriValve Registry included 312 high-risk patients with severe TR (76.4 +/- 8.5 years of age; 57% female; EuroSCORE II 9 +/- 8%) at 18 centers. Interventions included repair at the level of the leaflets (MitraClip, Abbott Vascular, Santa Clara, California; PASCAL Edwards Lifesciences, Irvine, California), annulus (Cardioband, Edwards Lifesciences; TriCinch, 4tech, Galway, Ireland; Trialign, Mitraling, Tewksbury, Massachusetts), or coaptation (FORMA, Edwards Lifesciences) and replacement (Caval Implants, NaviGate, NaviGate Cardiac Structures, Lake Forest, California). Clinical outcomes were prospectively determined during mid-term follow-up. A total of 108 patients (34.6%) had prior left heart valve intervention (84 surgical and 24 transcatheter, respectively). TR etiology was functional in 93%, and mean annular diameter was 46.9 +/- 9 mm. In 75% of patients the regurgitant jet was central (vena contracta 1.1 +/- 0.5; effective regurgitant orifice area 0.78 +/- 0.6 cm(2)). Pre-procedural systolic pulmonary artery pressure was 41 +/- 14.8 mm Hg. Implanted

devices included: MitraClip in 210 cases, Trialign in 18 cases, TriCinch first generation in 14 cases, caval valve implantation in 30 cases, FORMA in 24 cases, Cardioband in 13 cases, NaviGate in 6 cases, and PASCAL in 1. In 64% of the cases, TTVI was performed as a stand-alone procedure. Procedural success (defined as the device successfully implanted and residual TR). The report concluded that TTVI is feasible with different technologies, has a reasonable overall procedural success rate, and is associated with low mortality and significant clinical improvement. Mid-term survival is favorable in this high-risk population. Greater coaptation depth is associated with reduced procedural success, which is an independent predictor of mortality. <sup>14</sup>

Nickenig G et al., (2019) report the 6-month safety and performance of a transcatheter tricuspid valve reconstruction system in the treatment of moderate to severe functional TR in 30 patients enrolled in the TRI-REPAIR (TrIcuspid Regurgitation RePAIr With CaRdioband Transcatheter System) study. Between October 2016 and July 2017, 30 patients were enrolled in this single-arm, multicenter, prospective trial. Patients were diagnosed with moderate to severe, symptomatic TR in the absence of untreated left-heart disease and deemed inoperable because of unacceptable risk for open-heart surgery by the local heart team. Clinical, functional, and echocardiographic data were prospectively collected before and up to 6 months post-procedure. An independent core lab assessed all echocardiographic data, and an independent clinical event committee adjudicated the safety events. Mean patient age was 75 years, 73% were female, and 23% had ischemic heart disease. At baseline, 83% were in New York Heart Association (NYHA) functional class III to IV, and mean left ventricular ejection fraction was 58%. Technical success was 100%. Through 6 months, 3 patients died. Between 6 months and baseline, echocardiography showed average reductions of annular septolateral diameter of 9% (42 mm vs. 38 mm;  $p < 0.01$ ), proximal isovelocity surface area effective regurgitant orifice area of 50% (0.8 cm<sup>2</sup> vs. 0.4 cm<sup>2</sup>;  $p < 0.01$ ), and mean vena contracta width of 28% (1.2 cm vs. 0.9 cm;  $p < 0.01$ ). Clinical assessment showed that 76% of patients improved by at least 1 NYHA functional class with 88% in NYHA functional class I or II. Six-minute walk distance improved by 60 m ( $p < 0.01$ ), and Kansas City Cardiomyopathy Questionnaire score improved by 24 points ( $p < 0.01$ ). In conclusion, six-month outcomes show that the system performs as intended and appears to be safe in patients with symptomatic and moderate to severe functional TR. Significant reduction of TR through decrease of annular dimensions, improvements in heart failure symptoms, quality of life, and exercise capacity were observed. Further studies are warranted to validate these initial promising results. <sup>8</sup>

Professional Society Guidelines <sup>16-18</sup>

The 2017 position statement of the European Society of Cardiology Working Groups of Cardiovascular Surgery and Valvular Heart Disease: Management of Tricuspid Valve Regurgitation states that “Percutaneous tricuspid valve intervention (both repair and replacement) is still in its infancy but may become a reliable option in future, especially for high-risk patients with isolated primary TR or with secondary TR related to advanced left-sided heart valve disease.” <sup>16</sup>

**CODING INFORMATION:** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
33999	Unlisted procedure cardiac surgery

0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus
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HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

**REFERENCES**

**Government Agency**

- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: <http://www.cms.gov/medicare-coverage-database/>

**Peer Reviewed Publications**

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- Ranocchi F1, Nicolò F et al. Minimally invasive implantation of a Sapien 3 Ultra Valve in a degenerated tricuspid bioprosthesis. *J Card Surg*. 2020 Apr 25. doi: 10.1111/jocs.14572. [Epub ahead of print]

12. Regazzoli D, Ielasi A, Lanzillo G, et al. Sustained Reduction of Tricuspid Regurgitation after Percutaneous Repair with the MitraClip System in a Patient with a Dual Chamber Pacemaker. *JACC Cardiovasc Interv* 2017; 10:e147.
13. Schofer J, Bijuklic K, Tiburtius C, Hansen L, Groothuis A, Hahn RT. First-in-human transcatheter tricuspid valve repair in a patient with severely regurgitant tricuspid valve. *J Am Coll Cardiol* 2015;65:1190–1195.
14. Taramasso M, Alessandrini H, Latib A et al. Outcomes after current transcatheter tricuspid valve intervention: Mid-term results from the International TriValve Registry. *JACC Cardiovasc Interv.* 2019;Jan 28;12(2):155-165.
15. Wagner R, Daehnert I, Lurz P. Percutaneous pulmonary and tricuspid valve implantations: An update. *World J Cardiol.* 2015 Apr 26;7(4):167-77.

### Professional Society Guidelines

16. Antunes MJ, Rodríguez-Palomares J, Prendergast B, et al. Management of tricuspid valve regurgitation: Position statement of the European Society of Cardiology Working Groups of Cardiovascular Surgery and Valvular Heart Disease. *Eur J Cardiothorac Surg* 2017; 52:1022.
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18. AHA/ACC:
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### Other Resources

19. NIH Clinical Trials: Accessed at: <https://clinicaltrials.gov/ct2/home>
  - Edwards Cardioband Tricuspid Valve Reconstruction System Early Feasibility Study. ClinicalTrials.gov Identifier: NCT03382457
  - MitraClip for Severe TR (TVrepair). ClinicalTrials.gov Identifier: NCT02863549
  - TRI-REPAIR: TrIcuspid Regurgitation RePAiR With CaRdioband Transcatheter System (TRI-REPAIR). ClinicalTrials.gov Identifier: NCT02981953
  - TRILUMINATE Study with Abbott Transcatheter Clip Repair System in Patients with Moderate or Greater TR (TRILUMINATE). ClinicalTrials.gov Identifier: NCT03227757
  - The SPACER Trial - Repair of Tricuspid Valve Regurgitation Using the Edwards TricuSPid TrAnsCatheter REpaiR System (SPACER). ClinicalTrials.gov Identifier: NCT02787408
  - Transcatheter Repair of Tricuspid Regurgitation With Edwards Cardioband TR System Post Market Study (TriBAND) (TriBAND). ClinicalTrials.gov Identifier: NCT03779490
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22. AMR Peer Review Network: Policy reviewed by practicing board certified MD in Cardiovascular Disease, Interventional Cardiology, Internal Med. 4/19/20.

**Revision/Review History:**

2020: New Policy