

NO. 91597-R12

# TRANSCATHETER HEART VALVE PROCEDURES

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**Instructions for use:** This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

**Policy scope:** This medical policy outlines the coverage framework, clinical indications, and benefit applicability for transcatheter heart valve procedures, including transcatheter valve replacement and repair across the aortic, mitral, pulmonary, and tricuspid valves.

**Related policies:** None

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## I. MEDICAL NECESSITY CRITERIA

### A. Transcatheter Cardiac Valve **Replacement**

Priority Health has delegated utilization management of transcatheter aortic, mitral, pulmonary, and tricuspid cardiac valve replacement procedures to **TurningPoint Healthcare Solutions LLC**. Medical necessity for these procedures will be governed by the applicable TurningPoint Healthcare Solutions LLC medical policy.

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

### B. Transcatheter Cardiac Valve **Repair**

1. **Mitral:** Priority Health has delegated utilization management of select transcatheter mitral valve repair procedures to **TurningPoint Healthcare Solutions LLC**. Medical necessity for these procedures will be governed by the applicable TurningPoint Healthcare Solutions LLC medical policy.

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

2. **Tricuspid:** Considered medically necessary.

## II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the [CMS Online Manual System \(IOMs\)](#) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to [CMS Medicare Coverage Database](#).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare [Coverage Database website](#) for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
Transcatheter Aortic Valve Replacement (TAVR)	<a href="#">20.32</a>
Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation	<a href="#">20.33</a>
Transcatheter Tricuspid Valve Replacement (TTVR)	<a href="#">20.37</a>
Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)	<a href="#">20.38</a>
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

See also [Coverage with Evidence Development \(CED\)](#).

## III. BACKGROUND

**Transcatheter aortic valve implantation (TAVI)** is an alternative to current care, open heart, **aortic valve replacement (AVR)** in patients with severe aortic stenosis who are at high or prohibitive risk for operative mortality. Approximately 50,000 AVR procedures are performed annually in the United States, and the surgery is associated with significant improvement in the quality of life and prolonged survival. An estimated 32% of patients with severe aortic stenosis, however, are currently considered unsuitable candidates for open surgery. The prognosis for survival is poor in this patient subset. A recent study estimates that the 1- and 5-year survival rates are 62% and 32%, respectively, in non-surgically managed patients with severe aortic stenosis.

The U.S. pivotal PARTNER trial evaluated TAVI with the Sapien THV in two distinct patient populations: high-operative-risk patients (Cohort A) and medically inoperable patients (Cohort B). The randomized controlled trial (RCT) compared TAVI-TF or TAVI-TA (transapical) with surgical AVR in Cohort A, and TAVI-TF with current care nonsurgical management in Cohort B.

PARTNER results represent the only published RCT outcomes of TAVI with the Sapien valve. In Cohort B, TAVI-TF was significantly superior to nonsurgical therapy in reducing the 1-year mortality rates (31% versus 51%, respectively) and the combined endpoint of death or repeat hospitalization (43% versus 72%, respectively). TAVI-TF statistically bettered nonsurgical therapy in cardiac symptom improvement, but also was associated with a higher 30-day incidence of major vascular events. In Cohort A, TAVI was noninferior to AVR; 1-year mortality rates did not statistically differ (24.2% and 26.8%, respectively). However, rates of all neurologic events were significantly higher in the TAVI versus AVR groups at 30 days (5.5% versus 2.4%, respectively) and at 1 year (8.3% versus 4.3%, respectively). Major bleeding events and new-onset atrial fibrillation were significantly more frequent for AVR than for TAVI.

The Melody Transcatheter Pulmonary Valve and the Ensemble Transcatheter Delivery System received FDA approval in 2014.

A normal aortic valve area is greater than 2 cm<sup>2</sup>. By valve area alone, if the aortic valve area is between 1.5 and 2 cm<sup>2</sup>, the stenosis is mild; if the valve area is between 1 and 1.5 cm<sup>2</sup>, the stenosis is moderate. Severe AS is defined as an aortic velocity of 4 m/s or greater, a mean pressure gradient of 40 mmHg or greater, or an aortic valve area of 1 cm<sup>2</sup> or less. In the presence of a high velocity or gradient, valve area calculations are not always necessary. Typically, the aortic valve area will be 1 cm<sup>2</sup> or less, but factors such as body size, coexisting aortic regurgitation, or operator technique can affect valve area determinations. Valve area calculations, in addition to velocity or pressure gradient measurements, are important to confirm severe AS in the presence of a low ejection fraction or stroke volume.

An aortic valve area index (indexed aortic valve area) is calculated by dividing the aortic valve area by the body surface area. This measurement accounts for variations in body size among patients with aortic stenosis. For example, a valve area indicating moderate stenosis in a large patient may be considered severely stenotic when adjusted for size, while a valve area indicating moderate stenosis in a small patient may be considered mildly stenotic when adjusted for size.

The TriClip G4 Transcatheter Edge-to-Edge Repair System (TriClip, Abbott Medical) 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.*

The TriClip transcatheter edge-to-edge device is designed specifically for minimally invasive treatment of symptomatic, severe tricuspid regurgitation who are at intermediate or higher surgical risk.

The TriClip is engineered for use during tricuspid transcatheter edge-to-edge repair (T-TEER) for treatment of tricuspid regurgitation (TR). The system comprises a single-use steerable guide catheter (designed for direct access to the tricuspid valve and precise positioning) and the TriClip G4 delivery system; a stabilizer, lift, and support plate can be reused. The TriClip implants have nitinol grippers and a polyester cover intended to promote tissue growth. The implants are available in several sizes. Optimized features of the G4 system include a wide-grasp opening for full-depth leaflet insertion, a design that distributes retention forces along the whole length of the leaflet, and either 4 or 6 rows of short frictional elements for leaflet engagement without trauma induction.

The TriClip implants are placed under general anesthesia using femoral access to the right atrium of the heart. Real-time imaging, typically transesophageal echocardiography and fluoroscopy, is used to guide placement.

#### IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
<a href="#">American College of Cardiology (ACC)</a> <a href="#">American Heart Association (AHA)</a>	<a href="#">2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease (December 17, 2020)</a>
<a href="#">American College of Cardiology</a>	<a href="#">Transcatheter Heart Valve Handbook: A Surgeons' and Interventional Council Review (2018)</a>
<a href="#">American Heart Association</a>	<a href="#">The Tricuspid Valve: A Review of Pathology, Imaging, and Current Treatment Options: A Scientific Statement From the American Heart Association (April 2024)</a>
European Society of Cardiology (ESC) European Association for Cardio-Thoracic Surgery (EACTS)	<a href="#">2025 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the task force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) (August 2025)</a>
<a href="#">National Institute for Health and Care Excellence (NICE)</a>	<a href="#">Transcatheter tricuspid valve leaflet repair for tricuspid regurgitation. Interventional procedures guidance IPG731 (July 2022)</a>
Chinese Minimally Invasive Cardiovascular Surgery Committee (CMICS)	<a href="#">2022 CMICS Expert Consensus on the Management of Isolated Tricuspid Regurgitation after Left-Sided Valve Surgery (April 2023)</a>

**V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)**

See [U.S. Food & Drug Administration \(FDA\) Medical Device Databases](#) for the most current information.

The [Product Classification Database](#) contains medical device names and associated information developed by the Center for Devices and Radiological Health (CDRH) in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.

Relevant Product Codes: Percutaneously delivered replacement valves

- [NPT](#): aortic valve, prosthesis, percutaneously delivered
- [NPU](#): prosthesis, mitral valve, percutaneously delivered
- [NPV](#): pulmonary valve prosthesis percutaneously delivered
- [NPW](#): percutaneously delivered prostheses and tricuspid valves

Relevant Product Codes: Percutaneously delivered valve repair devices

- [NPS](#): tricuspid valve repair device, percutaneously delivered

Tricuspid Valve Repair Device, Percutaneously Delivered	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
<a href="#">TriClip™ System</a> (Abbott Medical)	<a href="#">P230007</a> (S001 – S018)	04/01/2024 (05/09/2024 – 10/17/2025)

**VI. CODING**

**ICD-10 Codes that may support medical necessity**

- I05.1 Rheumatic mitral insufficiency
- I34.0 Nonrheumatic mitral (valve) insufficiency
- I35.0 – I35.9 Nonrheumatic aortic valve disorders
- I37.0 – I37.9 Nonrheumatic pulmonary valve
- Q22.1 Congenital pulmonary valve stenosis
  
- I07.1 Rheumatic tricuspid insufficiency
- I07.2 Rheumatic tricuspid stenosis and insufficiency
- I08.1 Rheumatic disorders of both mitral and tricuspid valves
- I08.2 Rheumatic disorders of both aortic and tricuspid valves
- I08.3 Combined rheumatic disorders of mitral, aortic and tricuspid valves
- I36.1 Nonrheumatic tricuspid (value) insufficiency
- I36.2 Nonrheumatic tricuspid (value) stenosis and insufficiency
- Q22.8 Other congenital malformations of tricuspid value

**CPT/HCPCS Codes**

Transcatheter **aortic** valve **replacement** (TurningPoint Healthcare Solutions LLC)

See applicable **TurningPoint Healthcare Solutions LLC** medical policy for medical necessity criteria). *Prior Authorization required.*

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

- 33361 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
- 33362 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
- 33363 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
- 33364 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
- 33365 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (eg, median sternotomy, mediastinotomy)
- 33366 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)
- 33367 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)
- 33368 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (eg, femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
- 33369 Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

#### Transcatheter **mitral** valve **replacement** (TurningPoint Healthcare Solutions LLC)

See applicable **TurningPoint Healthcare Solutions LLC** medical policy for medical necessity criteria). *Prior Authorization required.*

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

- 0483T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; percutaneous approach, including transseptal puncture, when performed (Covered for Medicare only)
- 0484T Transcatheter mitral valve implantation/replacement (TMVI) with prosthetic valve; transthoracic exposure (eg, thoracotomy, transapical)

#### Transcatheter **pulmonary** valve **replacement** (TurningPoint Healthcare Solutions LLC)

See applicable **TurningPoint Healthcare Solutions LLC** medical policy for medical necessity criteria). *Prior Authorization required.*

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

33477 Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

Transcatheter **tricuspid** valve **replacement** (TurningPoint Healthcare Solutions LLC)

See applicable **TurningPoint Healthcare Solutions LLC** medical policy for medical necessity criteria). *Prior Authorization required.*

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

0646T Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed

Transcatheter **mitral** valve **repair** (TurningPoint Healthcare Solutions LLC)

See applicable **TurningPoint Healthcare Solutions LLC** medical policy for medical necessity criteria). *Prior Authorization required.*

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

33418 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis *Covered for Medicare under CED rules and criteria*

33419 Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure) *Covered for Medicare, under CED rules and criteria*

0345T Transcatheter mitral valve repair percutaneous approach via the coronary sinus (*Not Covered for Medicaid*)

Transcatheter **tricuspid** valve **repair** (Priority Health)

See also [TRICLIP™ TRANSCATHETER EDGE-TO-EDGE REPAIR \(TEER\) CODING GUIDE](#)

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)

**Not separately payable**

33370 Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological

supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)

93355 Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D

### **Not covered**

0544T Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture

0545T Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach

0643T Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach

0645T Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed

## **VII. MEDICAL NECESSITY REVIEW**

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the [Priority Health Provider Manual](#).

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

## **VIII. APPLICATION TO PRODUCTS**

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO:** For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the [Michigan Medicaid Fee Schedule](#). If there is a discrepancy between this policy and the [Michigan Medicaid Provider Manual](#), the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

## IX. REFERENCES

### Guidelines/Position Statements

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### Tricuspid valve repair

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