Priority Health

MEDICAL POLICY
No. 91597-R11

TRANSCATHETER HEART VALVE PROCEDURES

Effective Date: March 1, 2025

Review Dates: 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 5/19, 11/19, 5/20, 5/21, 5/22, 5/23, 5/24, 2/25

Date Of Origin: April 11, 2012

Status: Current

Summary of Changes

Clarifications:

- Utilization management and medical necessity criteria around transcatheter cardiac valve replacements and repairs have been clarified.
- Any procedures or interventions that are outside the scope of **transcatheter** heart valve procedures have been removed.

I. POLICY/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 (see Section **II. MEDICAL NECESSITY REVIEW** for guidance on accessing TurningPoint Healthcare Solutions LLC medical policies).

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 (see Section **II. MEDICAL NECESSITY REVIEW** for guidance on accessing TurningPoint Healthcare Solutions LLC medical policies, as well as Section **V. CODING INFORMATION**).
2. **Tricuspid**: Considered medically necessary.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, 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, please refer to the Priority Health Provider Manual.

To access TurningPoint guidelines policies: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

III. APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, 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.***

IV. DESCRIPTION

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^2. By valve area alone, if the aortic valve area is between 1.5 and 2 cm^2, the stenosis is mild; if the valve area is between 1 and 1.5 cm^2, 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^2 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^2 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.

V. CODING INFORMATION

ICD-10 Codes that may apply:

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

CPT/HCPCS Codes:

Transcatheter cardiac valve **replacement** (see applicable TurningPoint Healthcare Solutions LLC medical policy for medical necessity criteria). *Prior Authorization required*.

To access TurningPoint guidelines policies: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Aortic

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)

Mitral

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)

Pulmonary

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

Tricuspid

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 cardiac valve **repair**

Mitral

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

To access TurningPoint guidelines policies: 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)*

Tricuspid

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

VI. REFERENCES

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