**02-33000-33**

**Original Effective Date: 08/15/13**

**Reviewed: 07/24/25**

**Revised: 08/15/25**

# Subject: Transcatheter Pulmonary Valve Implantation

**THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.**



## DESCRIPTION:

Transcatheter pulmonary valve implantation (TPVI) has been proposed as a less invasive alternative to open surgical pulmonary valve replacement or reconstruction for right ventricular outflow tract (RVOT) obstruction. Percutaneous pulmonary valve replacement may be indicated for congenital pulmonary stenosis. Pulmonary stenosis or regurgitation in a patient with congenital heart disease (CHD) who has previously undergone RVOT surgery is additional indications. Patients with prior CHD repair are at risk of needing repeated reconstruction procedures.

Several transcatheter pulmonary valve device systems have received FDA approval (e.g., Melody Transcatheter Pulmonary Valve (TPV) and the Ensemble Transcatheter Valve Delivery System, Edwards SAPIEN XT Transcatheter Heart Valve (THV) Systems).

**Summary and Analysis of Evidence:** Sinha et al (2019) Patients with dysfunctional right ventricular outflow tracks comprise a large portion of patients with severe congenital heart disease. Transcatheter pulmonary valve replacement in patients with dysfunctional right ventricular outflow tracks is feasible, safe, and efficacious.

Cheatman et al (2015) Studies of transcatheter pulmonary valve (TPV) replacement with the Melody valve have demonstrated good short-term outcomes. TPV replacement with the Melody valve provided good hemodynamic and clinical outcomes up to 7 years after implantation.

Balzer et al (2019) Right ventricular outflow tract (RVOT) dysfunction is common following surgical repair of tetralogy of Fallot and other forms of complex congenital heart disease. This results in pulmonary stenosis or regurgitation and may ultimately lead to right ventricular (RV) failure and dysrhythmias. Transcatheter valve technologies are now available to treat certain patients with RVOT dysfunction. Current devices include the Medtronic Melody valve and the Edwards Lifesciences SAPIEN

XT. Although these valves are approved for use in dysfunctional circumferential RVOT conduits, they are increasingly being used off label for nonconduit outflow tracts. Procedural complications include but are not limited to conduit rupture and coronary compression. Longer-term complications include stent fracture and endocarditis. Outcomes with these valves have demonstrated durable relief of stenosis and regurgitation.

## POSITION STATEMENT:

Transcatheter pulmonary valve implantation using a Food and Drug Administration (FDA) device **meets the definition of medical necessity** for members with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation for the following indications:

- Members with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation; **OR**
- Members with native or patched RVOT with at least moderate pulmonic regurgitation; **OR**
- Members with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); **OR**
- Members with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

The Melody transcatheter pulmonary valve and the Ensemble Transcatheter Valve Delivery System **meets the definition of medical necessity** as an adjunct to surgery in the management of pediatric and adult members with the following clinical conditions:

1. Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted, **AND**
2. Dysfunctional RVOT conduits with clinical indication for intervention, and either:
    a. Regurgitation: ≥ moderate regurgitation, **OR**
    b. Stenosis: mean RVOT gradient ≥ 35 mm Hg

Transcatheter pulmonary valve implantation is considered **experimental or investigational** for all other indications. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## BILLING/CODING INFORMATION:

### CPT Coding

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

## REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Advantage products:** No Local Coverage Determination (LCD) and/or National Coverage Determinations (NCD) was found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

## DEFINITIONS:

No guideline specific definitions apply.

## RELATED GUIDELINES:

**Transcatheter Aortic Valve Replacement, 02-33000-32**

## OTHER:

Other terms used to describe transcatheter pulmonary valve implantation:

**Note:** The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

CoreValve™ System (aortic valve)
Edwards SAPIEN® transcatheter heart valve (aortic valve)
Medtronic Melody (pulmonary valve)
Percutaneous pulmonary valve implantation (PPVI)
Transcatheter pulmonary valve replacement (TPVR)
Harmony™ transcatheter pulmonary valve (TPV)

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/24/25.

## GUIDELINE UPDATE INFORMATION:

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| 08/15/13 | New Medical Coverage Guideline. |
| 08/15/14 | Scheduled review: position statement unchanged, references updated. |
| 11/01/15 | Revision: ICD-9 Codes deleted. |
| 01/01/16 | Annual HCPCS code update. Deleted 0262T. Added 33477. |

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| 09/15/18 | Revised position statement; added transcatheter pulmonary valve implantation for members with congenital heart disease and current right ventricular outflow tract obstruction or regurgitation, including indications. Deleted ICD-10 codes. Updated description and references. |
| 09/15/20 | Review; no change to position statement. Updated references. |
| 10/15/22 | Review; revised position statement. Updated references. |
| 05/25/23 | Update to Program Exceptions section. |
| 05/15/24 | Position statements maintained. Revised program exception. |
| 08/15/24 | Review; no change to position statement. Updated references. |
| 08/15/25 | Review; no change to position statement. Updated references. |