

02-33000-33

Original Effective Date: 08/15/13

Reviewed: 08/23/18

Revised: 09/15/18

## 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.

[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

### **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).

### **POSITION STATEMENT:**

Transcatheter pulmonary valve implantation 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:  $\geq$  moderate regurgitation, **OR**
  - b. Stenosis: mean RVOT gradient  $\geq$  35 mm Hg

Transcatheter pulmonary valve implantation is considered **experimental or investigational** for all other indications. There is insufficient clinical evidence published in the peer-reviewed literature on the off-label use of TPVI, including implantation of a non FDA-approved valve, or use of an approved valve for a non FDA-approved indication.

### **BILLING/CODING INFORMATION:**

#### **CPT Coding**

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:** The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Noncovered Services L33777 located at fcso.com.

### **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)

## **REFERENCES:**

1. Bhatt AB, Foster E, Kuehl K et al. Congenital heart disease in the older adult: a scientific statement from the American Heart Association. *Circulation*. 2015 May; 131(21):1884-1931.
2. Blue Cross Blue Shield Association Medical Policy Reference Manual 7.01.131 Transcatheter Pulmonary Valve Implantation, 05/18.
3. Boudjemline Y, Malekzadeh-Milani S, Patel M et al. Predictors and outcomes of right ventricular outflow tract conduit rupture during percutaneous pulmonary valve implantation: a multicentre study. *EuroIntervention*. 2016 Jan; 11(9):1053-1062.
4. Chatterjee A, Bajaj NS, McMahon WS et al. Transcatheter pulmonary valve implantation: a comprehensive systematic review and meta-analyses of observational studies. *Journal of the American Heart Association*. 2017 Aug; 6(8). pii: e006432.
5. Cheatham JP, Hellenbrand WE, Zahn EM et al. Clinical and hemodynamic outcomes up to 7 years after transcatheter pulmonary valve replacement in the US melody valve investigational device exemption trial. *Circulation*. 2015 Jun; 131(22):1960-1970.
6. Gillespie M, McElhinney DB, Kreutzer J et al. Transcatheter pulmonary valve replacement for right ventricular outflow tract conduit dysfunction after the Ross procedure. *Annals of Thoracic Surgery*. 2015 Sep; 100(3):996-1002.
7. Gillespie MJ, Rome JJ, Levi DS, Williams RJ, Rhodes JF, Cheatham JP, Hellenbrand WE, Jones TK, Vincent JA, Zahn EM, McElhinney DB. Melody valve implant within failed bioprosthetic valves in the pulmonary position: a multicenter experience. *Circ Cardiovasc Interv*. 2012 Dec; 5(6):862-70.
8. Hasan BS, McElhinney DB, Brown DW, Cheatham JP, Vincent JA, Hellenbrand WE, Jones TK, Zahn EM, Lock JE. Short-term performance of the transcatheter Melody valve in high-pressure hemodynamic environments in the pulmonary and systemic circulations. *Circ Cardiovasc Interv*. 2011 Dec;4(6):615-20.
9. Hijazi ZM, Ruiz CE, Zahn E et al. SCAI/AATS/ACC/STS operator and institutional requirements for transcatheter valve repair and replacement, Part III: pulmonic valve. *Journal of the American College of Cardiology*. 2015 Jun; 65(23):2556-2563.
10. McElhinney DB, Cabalka AK, Aboulhosn JA et al. Transcatheter Tricuspid Valve-in-Valve Implantation for the Treatment of Dysfunctional Surgical Bioprosthetic Valves: An International, Multicenter Registry Study. *Circulation*. 2016 Apr; 133(16):1582-1593.
11. McElhinney DB, Cheatham JP, Jones TK, Lock JE, Vincent JA, Zahn EM, Hellenbrand WE. Stent fracture, valve dysfunction, and right ventricular outflow tract reintervention after transcatheter pulmonary valve implantation: patient-related and procedural risk factors in the US Melody Valve Trial. *Circ Cardiovasc Interv*. 2011 Dec ;4(6):602-14.
12. McElhinney DB, Hellenbrand WE, Zahn EM, Jones TK, Cheatham JP, Lock JE, Vincent JA. Short- and medium-term outcomes after transcatheter pulmonary valve placement in the expanded multicenter US melody valve trial. *Circulation*. 2010 Aug;122(5):507-16.

13. National Guideline Clearinghouse. Guideline Summary. Recommendations for delivery of care and ensuring access. In: ACC/AHA 2008 guidelines for the management of adults with congenital heart disease. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.
14. National Institute for Health and Clinical Excellence (NICE) Interventional Procedure Guidance 436. Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction. January, 2013.
15. Nishimura RA, Otto CM, Bonow RO et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Journal of the American College of Cardiology. 2017 Jul; 70(2):252-289.
16. Nishimura RA, Otto CM, Bonow RO et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Journal of the American College of Cardiology. 2014 Jun; 63(22):e57-185.
17. Thyregod HG, Søndergaard L, Ihlemann N, Franzen O, Andersen LW, Hansen PB, Olsen PS, Nissen H, Winkel P, Gluud C, Steinbrüchel DA. The Nordic aortic valve intervention (NOTION) trial comparing transcatheter versus surgical valve implantation: study protocol for a randomised controlled trial. Trials. 2013 Jan 9;14:11.
18. Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA, del Nido P, Fasules JW, Graham TP, Hijazi ZM, Hunt SA, King ME, Landzberg MJ, Miner PD, Radford MJ, Walsh EP, Webb GD, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Antman EM, Buller CD, Creager MA, Ettinger SM, Halperin JL, Hunt SA, Krumholz HM, Kushner FG, Lytle BW, Nishimura RA, Page RL, Riegel B, Tarkington LG, Yancy CW. Recommendations for delivery of care and ensuring access. In: ACC/AHA 2008 guidelines for the management of adults with congenital heart disease. J Am Coll Cardiol. 2008; 52(23):e151-73.
19. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Edwards SAPIEN XT™ Transcatheter Heart Valve P130009/S037, February 29, 2016.
20. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Melody™ Transcatheter Pulmonary Valve, models PB1016 and PB1018; Ensemble™ Transcatheter Valve Delivery System February 24, 2017.
21. Webb JG, Wood DA, Ye J, Gurvitch R, Masson JB, Rodés-Cabau J, Osten M, Horlick E, Wendler O, Dumont E, Carere RG, Wijesinghe N, Nietlispach F, Johnson M, Thompson CR, Moss R, Leipsic J, Munt B, Lichtenstein SV, Cheung A. Transcatheter valve-in-valve implantation for failed bioprosthetic heart valves. Circulation. 2010 Apr ;121(16):1848-57.
22. Zahn EM, Hellenbrand WE, Lock JE et al. Implantation of the Melody transcatheter pulmonary valve in patients with a dysfunctional right ventricular outflow tract conduit early results from the U.S. clinical trial. Journal of the American College of Cardiology. 2009 Oct; 54(18): 1722-1729.

### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the BCBSF Medical Policy & Coverage Committee on 08/23/18.

### **GUIDELINE UPDATE INFORMATION:**

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.
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.