# MEDICAL POLICY

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| **POLICY TITLE** | **TRANSCATHETER PULMONARY VALVE IMPLANTATION** |
| **POLICY NUMBER** | **MP 1.139** |

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| **CLINICAL BENEFIT** | ☐ MINIMIZE SAFETY RISK OR CONCERN.<br>☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.<br>☐ ASSURE APPROPRIATE LEVEL OF CARE.<br>☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.<br>☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.<br>☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| **Effective Date:** | **11/1/2024** |


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## I. POLICY

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Transcatheter pulmonary valve implantation may be considered **medically necessary** for individuals with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation including the following indications:

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

Transcatheter pulmonary valve implantation is considered **investigational** for all other indications as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

***Cross-reference:***

**MP 1.135** Transcatheter Aortic-Valve Implantation for Aortic Stenosis
**MP 1.153** Transcatheter Mitral Valve Procedures

## II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

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FEP PPO – Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

## III. DESCRIPTION/BACKGROUND

TOP

### CONGENITAL HEART DISEASE

Congenital heart disease, including tetralogy of Fallot, pulmonary atresia, and transposition of the great arteries, is generally treated by surgical repair at an early age. This involves reconstruction of the right ventricular outflow tract (RVOT) and pulmonary valve using a surgical homograft or a bovine-derived valved conduit. These repairs are prone to development of pulmonary stenosis or regurgitation over long periods of follow-up.

Because individuals with surgically corrected congenital heart disease repair are living into adulthood, RVOT dysfunction following initial repair has become more common. Calcification of the RVOT conduit can lead to pulmonary stenosis, while aneurysmal dilatation can result in pulmonary regurgitation. RVOT dysfunction can lead to decreased exercise tolerance, potentially fatal arrhythmias, and/or irreversible right ventricular dysfunction.

### Treatment

Interventions for RVOT dysfunction often require numerous repeat open heart procedures for patients who live into adulthood. Treatment options for pulmonary stenosis are open surgery with valve replacement, balloon dilatation, or percutaneous stenting. Interventions for pulmonary regurgitation are primarily surgical, either reconstruction of the RVOT conduit or replacement of the pulmonary valve. The optimal timing of these interventions is not well understood.

Transcatheter pulmonary valve replacement offers a less invasive treatment option for patients with prior surgery for congenital heart disease and RVOT dysfunction. It is possible that a less invasive valve replacement technique could spare patients from multiple repeat open heart procedures over long periods of follow-up.

### REGULATORY STATUS

Devices for transcatheter pulmonary valve implantation were initially cleared from marketing by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process or used off-label until approved by FDA through the premarket approval (PMA) process between 2015 and 2016 (see Table 1).

**Table 1. Regulatory Status of Transcatheter Pulmonary Valve Implantation Devices**

| Device | Manufacturer | Date Approved | PMA No. | Indications |
|---|---|---|---|---|
| Melody® Transcatheter Pulmonary Valve (TPV) | Medtronic | Jan 2010 | H080002 (HDE) | Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit |

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| Melody TPV | Medtronic | Jan 2015 | P140017 | Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit |
| Melody TPV | Medtronic | Feb 2017 | P140017/ S005 | Valve-in-valve for patients with a dysfunctional surgical bioprosthetic pulmonary valve |
| SAPIEN XT™ Transcatheter Heart Valve (pulmonic) | Edwards Lifesciences | Feb 2016 | P130009/ S037 | Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit |

HDE: humanitarian device exemption; PMA: premarket approval; RVOT: right ventricular outflow tract.

The Melody® Transcatheter Pulmonary Valve (TPV) and the Ensemble® Transcatheter Valve Delivery System are used together for percutaneous replacement of a dysfunctional pulmonary valve. The Melody® valve consists of a section of bovine jugular vein with an intact native venous valve. The valve and surrounding tissue are sutured within a platinum-iridium stent scaffolding. The transcatheter delivery system consists of a balloon-in-balloon catheter with a retractable sheath and distal cup into which the valve is placed. The procedure is performed on a beating heart without the use of cardiopulmonary bypass.

The Melody® valve is first crimped to fit into the delivery system. It is introduced through the femoral vein and advanced into the right side of the heart and put into place at the site of the pulmonary valve. The inner balloon is inflated to open the artificial valve, and then the outer balloon is inflated to position the valve into place.

In January 2010, the Melody® TPV and the Ensemble® Transcatheter Valve Delivery System (Medtronic) were approved by FDA under the HDE program for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that is 16 mm or greater in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
  - Regurgitation: moderate-to-severe regurgitation, or
  - Stenosis: mean RVOT gradient ≥35 mm Hg.

On January 27, 2015, approval of the Melody® system was amended to a PMA because FDA determined that the device represented a breakthrough technology. The PMA was based, in part, on 2 prospective clinical studies, the Melody TPV Long-term Follow-up Post Approval Study and the Melody TPV New Enrollment Post Approval Study.

On February 24, 2017, approval of the Melody® system was expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve).

The Edwards SAPIEN XT™ Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) is composed of a stainless-steel frame with bovine pericardial tissue leaflets and available in 23- and 26-mm sizes. It includes a delivery accessories system. On February 29, 2016, it was approved by FDA as a supplement "for use in pediatric and adult patients with a dysfunctional, noncompliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and:

- Pulmonary regurgitation ≥ moderate and/or
- Mean RVOT gradient ≥ 35 mmHg."

The approval for the pulmonic valve indication is a supplement to the 2014 PMA for use of the Edwards SAPIEN XT™ Transcatheter Heart Valve System for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis and who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons operative risk score ≥8% or at a ≥15% risk of mortality at 30 days).

FDA product code: NPV.

## IV. RATIONALE

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### SUMMARY OF EVIDENCE

For individuals who have a history of CHD and current RVOT obstruction who receive TPVI with an FDA-approved device and indication, the evidence includes prospective, interventional, noncomparative studies, and multiple prospective and retrospective case or cohort series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. Results of the case series have indicated that there is a high rate of procedural success and low procedural mortality, although the rates of serious procedural adverse events reported ranged from 3.0% to 7.4%. Most valves have demonstrated competent functioning by Doppler echocardiography at 6- to 12-month follow-ups, but complications (e.g., stent fractures, need for reinterventions) were reported in an FDA analysis at rates of 18% and 7%, respectively. Other publications with longer follow-up have reported stent fractures in up to 26% of patients; however, most stent fractures did not require reintervention. Studies with follow-up extending to a maximum of 7 years post-procedure have suggested that the functional and hemodynamic improvements are durable, but a relatively high proportion of patients (20%-30%) have required reintervention on the pulmonary valve. No comparative studies were identified, and there is no direct evidence that TPVI reduces future open-heart procedures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have a history of CHD and current RVOT obstruction who receive TPVI with a non-FDA-approved device or indication, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. There is limited evidence on the off-label use of

TPVI including the use of a non-FDA-approved valve or use of an approved valve for a non-FDA-approved indication. The published case series enrolled relatively few patients and are heterogeneous regarding devices used and indications for TPVI. The evidence is insufficient to determine the effects of the technology on health outcomes.

In patients who are not candidates for open surgery or who are at high risk for surgery due to other medical comorbidities, alternative treatment options are limited. Clinical vetting obtained in 2011 indicated near-uniform support for the use of TPVI in both groups of these patients. Based on this clinical vetting and evidence on short-term success, TPVI can be considered medically necessary for patients who are not candidates for open repair or who are at high risk for open repair.

Clinical input obtained in 2018 supports that the following indications provide a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice.

- Use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Use of TPVI for individuals with native or patched RVOT with at least moderate pulmonic regurgitation;
- Use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
- Use of TPVI for individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

## V. DEFINITIONS

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**CONGENITAL HEART DISEASE** is a heart abnormality presents at birth that can affect the heart walls, valves, or vessels

**PULMONARY VALVE** is the valve of the heart that lies between the right ventricle and the pulmonary artery

**VENTRICLE** is one of the bottom chambers of the heart that collect and pump blood to the body

## VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

## VII. DISCLAIMER

*Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Covered when medically necessary:**

| Procedure Codes | | | | | | | | |
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| 33477 | | | | | | | | |

| ICD-10-CM Diagnosis Code | Description |
|---|---|
| I37.0 | Nonrheumatic pulmonary valve stenosis |
| I37.1 | Nonrheumatic pulmonary valve insufficiency |
| I37.2 | Nonrheumatic pulmonary valve stenosis with insufficiency |
| I37.8 | Other nonrheumatic pulmonary valve disorders |
| I37.9 | Nonrheumatic pulmonary valve disorder, unspecified |
| I97.0 | Postcardiotomy syndrome |
| I97.110 | Postprocedural cardiac insufficiency following cardiac surgery |
| I97.130 | Postprocedural heart failure following cardiac surgery |
| I97.190 | Other postprocedural cardiac functional disturbances following cardiac surgery |
| Q20.5 | Discordant atrioventricular connection |
| Q21.3 | Tetralogy of Fallot |
| Q22.0 | Pulmonary valve atresia |
| Q22.1 | Congenital pulmonary valve stenosis |
| Q22.2 | Congenital pulmonary valve insufficiency |
| Q22.3 | Other congenital malformations of pulmonary valve |

| ICD-10-CM Diagnosis Code | Description |
|---|---|
| T82.01XA | Breakdown (mechanical) of heart valve prosthesis, initial encounter |
| T82.01XD | Breakdown (mechanical) of heart valve prosthesis, subsequent encounter |
| T82.01XS | Breakdown (mechanical) of heart valve prosthesis, sequela |
| T82.02XA | Displacement of heart valve prosthesis, initial encounter |
| T82.02XD | Displacement of heart valve prosthesis, subsequent encounter |
| T82.02XS | Displacement of heart valve prosthesis, sequela |
| T82.03XA | Leakage of heart valve prosthesis, initial encounter |
| T82.03XD | Leakage of heart valve prosthesis, subsequent encounter |
| T82.03XS | Leakage of heart valve prosthesis, sequela |
| T82.09XA | Other mechanical complication of heart valve prosthesis, initial encounter |
| T82.09XD | Other mechanical complication of heart valve prosthesis, subsequent encounter |
| T82.09XS | Other mechanical complication of heart valve prosthesis, sequela |
| T82.221A | Breakdown (mechanical) of biological heart valve graft, initial encounter |
| T82.221D | Breakdown (mechanical) of biological heart valve graft, subsequent encounter |
| T82.221S | Breakdown (mechanical) of biological heart valve graft, sequela |
| T82.222A | Displacement of biological heart valve graft, initial encounter |
| T82.222D | Displacement of biological heart valve graft, subsequent encounter |
| T82.222S | Displacement of biological heart valve graft, sequela |
| T82.223A | Leakage of biological heart valve graft, initial encounter |
| T82.228A | Other mechanical complication of biological heart valve graft, initial encounter |
| T82.228 | Other mechanical complication of biological heart valve graft, subsequent encounter |
| T82.228S | Other mechanical complication of biological heart valve graft, sequela |
| Z87.74 | Personal history of (corrected) congenital malformations of heart and circulatory system |

## IX. REFERENCES

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## X. POLICY HISTORY

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| **MP- 1.139** | **CAC 9/28/13 New policy** adopts BCBSA. Procedure is considered medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract (RVOT) dysfunction, who are not |

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| | good candidates for open repair. FEP variation added. Medicare variation added. Policy coded. |
| | **CAC 9/30/14 Consensus review**. No change to policy statements. Reference and rationale sections updated. |
| | **11/2/15 Administrative update.** LCD number changed from L31686 to L35094 due to Novitas update to ICD-10. |
| | **CAC 9/29/15 Consensus review**. No change to the policy statements. Reference and rationale update. Coding reviewed |
| | **1/18/16 Administrative update:** Added new 2016 code & removed end dated code (0262T). |
| | **CAC 9/27/16 Consensus review**. Description/Background, Regulatory Status, Rationale and Reference sections updated. Coding reviewed/updated. Variation reformatting completed. |
| | **CAC 11/28/17 Minor review**. Regulatory section updated to reflect FDA-approval of the Edwards Sapien XT™ Transcatheter Heart Valve Pulmonic References reviewed. Coding reviewed/updated. |
| | **5/31/18 Minor review.** The first policy statement changed to: Transcatheter pulmonary valve implantation is considered medically necessary for patients with congenital heart disease and current right ventricular outflow tract obstruction or regurgitation including the specified indications. Previously was medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract dysfunction, who are not good candidates for open repair. Coding reviewed. |
| | **4/3/19 Consensus review**. No changes to policy statements. References updated. |
| | **4/6/20 Consensus review**. No changes to policy statement. Corrected format of table. References, ICD10 codes and Background chart updated. |
| | **6/28/2021 Consensus review.** No changes to policy statement. Updated cross-references, summary of evidence, and references. No changes to coding. |
| | **08/10/2022 Consensus Review.** No changes to policy statement. New definitions. Updated references. No coding changes. |
| | **07/14/2023 Consensus Review.** No changes to policy stance. Updated references. |
| | **1/19/2024 Administrative updated**. Clinical benefit added. |