

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

[TOP](#)

Transcatheter pulmonary valve implantation is considered **medically necessary** for patients 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 conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP-1.135 Transcatheter Aortic-Valve Implantation for Aortic Stenosis

II. PRODUCT VARIATIONS

[TOP](#)

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.131, Transcatheter Pulmonary Valve Implantation. The FEP Medical Policy Manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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.¹

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.¹ 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.²

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
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

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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.³ 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 \geq 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

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

therapy (ie, Society of Thoracic Surgeons operative risk score $\geq 8\%$ or at a $\geq 15\%$ risk of mortality at 30 days).

FDA product code: NPV.

IV. RATIONALE

[TOP](#)

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 (eg, 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 postprocedure 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.

V. DEFINITIONS

[TOP](#)

N/A

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

VI. BENEFIT VARIATIONS

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

Capital BlueCross'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. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

[TOP](#)

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:

CPT Codes®								
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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
I97.0	Postcardiotomy syndrome
197.110	Postprocedural cardiac insufficiency following cardiac surgery

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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

IX. REFERENCES

[TOP](#)

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POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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X. POLICY HISTORY

[TOP](#)

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 good candidates for open repair. FEP variation added. Medicare variation added. Policy coded.
	CAC 9/30/14 Consensus. No change to policy statements. Reference and rationale sections updated.
	11/2/15 Administrative change. 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
	Administrative 1/18/16: Added new 2016 code & removed end dated code (0262T).

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

	<p>CAC 9/27/16 Consensus review. Description/Background, Regulatory Status, Rationale and Reference sections updated. Coding reviewed/updated. Variation reformatting completed.</p>
	<p>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.</p>
	<p>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.</p>

[Top](#)

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