

POLICY TITLE	TRANSCATHETER PULMONARY VALVE IMPLANTATION
POLICY NUMBER	MP-1.139

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I. POLICY

Transcatheter pulmonary valve implantation, when performed according to FDA-approved indications, 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 due to one or more of the following conditions:

- High-risk for surgery due to concomitant medical comorbidities; or
- Poor surgical candidate due to multiple prior thoracotomies for open heart surgery.

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

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
 [N] PPO
 [N] HMO
 [Y] SeniorBlue HMO**
 [Y] SeniorBlue PPO**

[N] Indemnity
 [N] SpecialCare
 [N] POS
 [Y] 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:
<http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980>

** Refer to Novitas Solutions Local Coverage Determination (LCD) L31686 Services That Are Not Reasonable and Necessary.

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III. DESCRIPTION/BACKGROUND

Transcatheter pulmonary valve implantation (TPVI) is an alternative to pulmonary valve replacement by open surgery. It is intended for patients who have previously had a pulmonary valve repair for congenital heart disease, in whom dysfunction of the repaired valve necessitates further intervention.

Description of 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 by means of 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.

As individuals with prior congenital heart disease repair are living longer into adulthood, the problem of 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.

Interventions for RVOT dysfunction often require repeat open heart surgery, resulting in numerous 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 through open surgery. The optimal timing of these interventions is not well understood.

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

Description of Technology. The Melody transcatheter pulmonary valve 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 is 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 the beating heart without 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 up the artificial valve, and then the outer balloon is inflated to position the valve into place.

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Regulatory Status

The Melody transcatheter pulmonary valve and the Ensemble Transcatheter Valve Delivery System, manufactured by Medtronic Heart Valves, Inc (Santa Ana, CA), received U.S. Food and Drug Administration (FDA) approval under the Humanitarian Device Exemption (HDE) Program on January 25, 2010. Approval was 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 was equal to or greater than 16 mm in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
 - Regurgitation: \geq moderate regurgitation, or
 - Stenosis: mean RVOT gradient ≥ 35 mm Hg

IV. RATIONALE

The published literature on transcatheter pulmonary valve implantation (TPVI) consists of small case series, which generally report on short-term outcomes. Some of the larger, representative publications are discussed in this literature review.

Studies using FDA-approved valves

The only device that currently has U.S. Food and Drug Administration (FDA) approval for transcatheter pulmonary valve implantation is the Melody™ valve (Medtronic Heart Valves, Inc., Santa Ana, CA). Approved indications include RVOT dysfunction, defined as pulmonic regurgitation (moderate or greater) or pulmonic stenosis (mean gradient of 35 mm Hg or higher). In addition, a circumferential RVOT conduit should exist that is equal to or greater than 16 mm in diameter when originally implanted.

US Melody TPV trial. The multicenter US Melody TPV trial is a prospective uncontrolled trial from 5 clinical sites that was designed to study the safety, procedural success, and short-term effectiveness of the Melody transcatheter pulmonary valve. (2, 3) This was the pivotal trial on which FDA approval for the Melody valve was based. The study was designed to follow 150 patients over a 5-year period. Eligibility criteria included a dysfunctional right ventricular outflow tract (RVOT) conduit or a dysfunctional bioprosthetic pulmonary valve, plus evidence of heart failure. For patients with New York Heart Association (NYHA) class I heart failure, a Doppler mean gradient of equal to or greater than 40 mm Hg or severe pulmonary regurgitation was required, and for patients with NYHA class II-IV heart failure, a mean gradient of equal to or greater than 35 mm Hg or moderate pulmonary regurgitation was required. These inclusion criteria generally were indications for pulmonary valve replacement. The primary outcomes were defined as procedural success, adverse events from the procedure, and effectiveness, as measured by the proportion of patients with acceptable valve function at 6 months.

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Interim results from this trial have been published. (2, 3) The most recent publication (2) reported on 136 patients who underwent attempted TPVI. A total of 124/136 patients (91.2%) had successful implantation. In 12 patients, implantation was not possible due to anatomic or other intra-procedural findings that precluded implantation. One death occurred as a result of the procedure (0.7%), and serious adverse events occurred in 8/136 patients (6%). Adverse events included coronary artery dissection, conduit rupture/tear, wide complex tachycardia, respiratory failure, femoral vein thrombosis, and perforation of the pulmonary artery.

A total of 94 patients had successful implantation and reached the 6-month follow-up time point at the time of publication. Acceptable valve function, defined as mild pulmonary regurgitation or less on echocardiography, was present in greater than 90% of patients. Right ventricular pressure and right ventricular outflow tract gradient improved following the procedure, and 71/94 (75.5%) were in NYHA class I heart failure at 6 months. Over the course of follow-up, stent fractures were diagnosed in 25/124 (20.2%) patients, and 9/124 (7.3%) required implantation of a second valve.

A secondary publication from the US Melody TPV trial focused on the change in exercise function following TPVI. (4) Patients completed a standardized cardiopulmonary regimen 2 months prior to TPVI and 6 months following TPVI. Results of pre- and post- exercise parameters were available for 94-114 patients, depending on the specific outcome. There were numerous physiologic outcome measures reported, with some of these showing a statistically significant change between the 2 time points, and others not showing a significant change. For example, there was a significant increase in the percent predicted maximal workload from 65.0% at baseline to 68.3% at follow-up ($p<0.001$) and a significant decrease in the ratio of minute ventilation to CO₂ production from 30.8 at baseline to 29.1 at follow-up ($p<0.001$). In contrast, there were no significant changes in peak oxygen consumption or in spirometric measures of pulmonary function. This study reports modest benefits in exercise parameters for patients treated with TPVI. The results are limited by the lack of a control group and by the large number of patients who did not have completed exercise results available (approximately one-third of total).

Italian Society of Pediatric Cardiology Registry. (5) Butera et al published outcomes of 63 patients who were enrolled in this prospective, multicenter registry. Implantation was successful in 97% (61/63) of patients. There was one early death following TPVI, and peri-procedural complications occurred in 14% (9/63). Two complications were considered major, these were stent migration requiring re-intervention and ventricular fibrillation treated with external cardioversion. The median right ventricular systolic pressure was reduced from 80 at baseline to 20 ($p<0.001$) following the procedure, and 60% (38/63) of patients had either grade 0 or grade 1 pulmonary regurgitation. At a median follow-up of 30 months, an additional 3 patients died and 6 patients had major complications. These complications included Melody valve endocarditis (n=2), stent fracture requiring re-intervention (n=2), and herpes virus encephalitis (n=2). There were also 8 patients (13%) who had stent fractures that did not

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require intervention. Freedom from valve failure or re-intervention at last follow-up was estimated to be 81.4%.

Lurz et al.(6) This publication reported on 163 patients who underwent attempted TPVI from 4 clinical centers in Europe. Eligibility for the procedure included elevated right ventricular (RV) systolic pressure, increased RVOT dimensions, and either symptoms or evidence of severe RV dysfunction. Procedural success was achieved in 155/163 patients (95.1%). Procedural complications occurred in 12/163 (7.4%), 8 of which were considered serious and 5 of which required open surgery.

The median follow-up was 28.4 months. Over the course of follow-up, 4/155 patients (2.6%) died, and an additional 5/155 patients (3.2%) developed infective endocarditis. At 12 months' follow-up, greater than 90% of patients had absent or mild valve dysfunction as measured by echocardiography.

Eicken et al.(7) This study reported on 102 consecutive patients (mean age 21.5 years) undergoing transcatheter pulmonary valve implantation at 2 centers in Germany. Eligibility for the procedure included RVOT dysfunction with evidence of RV compromise or increased RV pressure. There was one death (1.0%) that occurred as a result of compression of the left coronary artery. Two patients (2.0%) had evidence of stent fracture immediately post-procedure, and one additional patient (1.0%) developed infective endocarditis at 6 month follow-up. At a median follow-up of 357 days, there was a significant decrease in the RVOT gradient from a median of 36 mm Hg to 15 mm Hg ($p<0.0001$). However, there was no significant change in exercise capacity as measured by maximal oxygen uptake.

Other case series reported on smaller numbers of patients, with patient populations ranging from 7-59. (8-12) These publications reported generally similar results as the larger series, with high procedural success and relatively low rates of serious complications. One of these trials reports follow-up for up to 2 years; no studies were identified that provide longer follow-up data.

Non-FDA approved uses of TPVI

There are a variety of potential off-label uses of TPVI that have been reported in the literature. These include use of devices that are not FDA-approved, and use of approved devices for non-FDA-approved indications.

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Boshoff et al described the off-label uses in 21 patients treated with the Melody valve and 2 patients treated with the Edwards SAPIEN® pulmonic valve. (13) These included use in native RVOT obstruction, in conduits that were smaller than the FDA-labeled indications, and in large RVOT with a dynamic outflow aneurysm. There were no deaths or major procedural complications reported for these patients. Clinical outcome data were lacking or very limited in this publication.

Case series reporting on the use of the Edwards SAPIEN® Pulmonic Valve for RVOT obstruction have been published. Kenny et al. reported on a Phase I multicenter study of the Sapien pulmonic valve in 36 patients from 4 clinical centers. (14) Procedural success was reported in 97% of patients. Procedural complications occurred in 19% of patients (7/36), including valve migration (n=3), pulmonary hemorrhage (n=2), ventricular fibrillation (n=1), and stent migration (n=1). At 6 month follow-up there were no deaths and 75% of patients (27/36) were in NYHA class I, compared to 14% at baseline. Freedom from re-intervention at 6 months was 97%.

Faza et al. reported on 20 patients who underwent successful implantation of the Edwards SAPIEN® pulmonic valve at one clinical center. (15) There were no periprocedural deaths, and all but one patient had no or trivial pulmonic regurgitation on latest follow-up. A comparison of hemodynamic parameters in these 20 patients was made with 13 patients who were treated with the Melody valve. Immediately following the procedure, the transvalvular gradient was similar between groups. At last follow-up, the mean residual transvalvular gradient was higher for patients receiving the SAPIEN® valve (18.4 mm Hg versus 11.2 mm Hg, p=0.016), but this difference was no longer present when patients were matched for length of follow-up.

Adverse events

In addition to the adverse events reported in the case series, several publications have focused on adverse events following TPVI.

The FDA reviewed results from the US Melody TPV trial as part of the FDA approval process and reported detailed data on complications from the procedure. (16) At that time, data were available for 99 patients enrolled between January 2007 and December 2008. A total of 90 patients were deemed suitable for implantation following catheterization, and 87/90 patients had successful implantation. There was one procedural-related death (1.1%). The following table is adapted from the FDA summary of safety and probable benefit:

Device-related adverse effects (N=89 subjects)

Event	Subjects with	Freedom from event at 12mth
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Event (SE)

Stent fracture (all)	16 (18%)	77.1% (7.5)
Minor ¹	11 (12%)	84.1% (6.7)
Major ¹	5 (6%)	90.6% (5.2)
Valve stenosis	6 (7%)	90.5% (4.8)
Worsening tricuspid regurgitation	1 (1%)	100% (--)
Reintervention ²	6 (7%)	93.5% (4.3)
Reoperation	1 (1%)	98.6% (2.2)

¹ Stent fractures that did not require intervention were defined as minor; those that required reintervention were defined as major

² Reinterventions were balloon angioplasty in one patient; repeat implantation of a second TPV in 5 patients

There were 64 patients in the FDA analysis who reached 6 months of follow-up. Of these, 56/64 (87.5%) had acceptable hemodynamic function of the valve by Doppler echocardiography. At 6 months, approximately 75% of patients were in NYHA class I, and 25% were in NYHA class II. Pulmonary regurgitation that was mild or worse was present in 6.2% of patients.

Another publication focusing on adverse events in the US Melody TPV trial was published in 2011. (17) This publication reported on adverse events at a median follow-up of 30 months in 150 patients. Stent fracture occurred in 26% (39/150) of patients. The estimated freedom from stent fracture was 77% at 14 months and 60% at 39 months. Freedom from re-interventions for all patients was estimated to be 86% at 27 months, and freedom from re-interventions for patients with stent fracture was estimated at 49% at 2 years.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests for clinical vetting in 2011, input was received from 5 academic medical centers. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

Overall response to whether TPVI was investigational was mixed, with 2 of 5 reviewers indicating they agree with the investigational status, and 3 reviewers who indicated it was a

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split decision. The majority of reviewers (4/5) indicated in their written response that there was a subpopulation of patients who were high risk for surgery or who were not candidates for surgery, in whom there were no other available options. These reviewers felt that TPVI was a viable alternative that offered potential benefit for these patients.

Summary

Transcatheter pulmonary valve implantation received FDA approval under the Humanitarian Device Exception program in January 2010 for patients with previous repair of congenital heart disease and right ventricular outflow tract (RVOT) obstruction. There is currently a lack of high-quality evidence evaluating outcomes of this procedure for the indicated population. No randomized controlled trials (RCTs) have been performed, and there are no controlled trials that compare transcatheter valve implantation to available alternatives. The available evidence consists of case series of patients with RVOT dysfunction who require intervention.

The results of the case series indicate that there is a high rate of procedural success and low procedural mortality. The rate of serious procedural adverse events reported in these series ranges from 3.0-7.4%. At 6-12 months of follow-up, there is evidence that the majority of valves demonstrate competent functioning by Doppler echocardiography, with most patients in NYHA functional class I or II. Complications at 6 month follow-up, such as stent fractures and the need for re-interventions, were reported by the FDA analysis to occur at rates of 18% and 7%, respectively. Other publications with longer follow-up have reported stent fractures in up to 26% of patients, however the majority of stent fractures have not required re-intervention. There is no direct evidence to demonstrate that TPV implantation leads to a reduction in future open heart procedures.

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 received in 2011 indicated near uniform support for use of TPVI in patients who were not candidates for open repair or who were at high risk for open surgery. Based on this clinical vetting and the evidence on short-term success, TPVI can be considered medically necessary for patients who are not candidates for open repair or who are high risk for open repair.

There is very limited published evidence 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. For these off-label uses, TPVI is considered investigational.

Practice Guidelines and Position Statements

None

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V. DEFINITIONS**N/A****VI. BENEFIT VARIATIONS**

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 for benefit information.

VII. DISCLAIMER

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

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IX. CODING INFORMATION

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®								
0262T								

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HCPCS Code	Description
N/A	

ICD-9-CM Diagnosis Code*	Description
429.4	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach
745.12	Corrected transposition of great vessels
745.2	Tetralogy of Fallot
746.00-746.09	Congenital anomalies of pulmonary valve code range
996.71	Other complications of internal (biological) (synthetic) prosthetic device, implant, and graft – due to heart valve prosthesis
V43.3	Organ or tissue replaced by other means – heart valve

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
I97.0	Postcardiotomy syndrome
197.110	Postprocedural cardiac insufficiency following cardiac surgery
I97.111	Postprocedural cardiac insufficiency following other surgery
I97.120	Postprocedural cardiac arrest following cardiac surgery

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ICD-10-CM Diagnosis Code*	Description
I97.121	Postprocedural cardiac arrest following other surgery
I97.130	Postprocedural heart failure following cardiac surgery
I97.131	Postprocedural heart failure following other surgery
I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
I97.191	Other postprocedural cardiac functional disturbances following other surgery
Q20.5	Discordant atrioventricular connection
Q21.3	Tetralogy of Fallot
Q22.3	Other congenital malformations of pulmonary valve
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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X. POLICY HISTORY

MP- 1.139	CAC 9-13 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.
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