



# Louisiana

## Transcatheter Pulmonary Valve Implantation

Policy # 00576

Original Effective Date: 10/18/2017

Current Effective Date: 09/14/2020

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services Are Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider transcatheter pulmonary valve implantation for patients with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation including the following indications to be **eligible for coverage\*\***:

- 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).

### When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers transcatheter pulmonary valve implantation for all other indications to be **investigational**.\*

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### **Background/Overview**

#### **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.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Devices for transcatheter pulmonary valve implantation were initially cleared from marketing by the U.S. 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).

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Table 1. Regulatory Status of Transcatheter Pulmonary Valve Implantation Devices

Device	Manufacturer	Date Approved	PMA No.	Indications
Melody <sup>®‡</sup> 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 <sup>™</sup> 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<sup>®‡</sup> Transcatheter Pulmonary Valve (TPV) and the Ensemble<sup>®‡</sup> 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.

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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  $\geq 35$  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™<sup>†</sup> 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  $\geq 35$  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  $\geq 8\%$  or at a  $\geq 15\%$  risk of mortality at 30 days).

FDA product code: NPV.

## **Rationale/Source**

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Transcatheter pulmonary valve implantation (TPVI) is 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 are additional indications. Patients with prior CHD repair are at risk of needing repeated reconstruction procedures.

For individuals who have a history of CHD and current RVOT obstruction who receive TPVI with a FDA-approved device and indication, the evidence includes prospective, interventional, non-comparative 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 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.

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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.

## **Supplemental Information**

### **Clinical Input From Physician Specialty Societies and 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.

### **2018 Input**

In response to requests, clinical input on the use of transcatheter pulmonary valve implantation (TPVI) was received from 2 specialty society-level respondents while this policy was under review in 2018. The combined clinical input response incorporated input from a panel including physicians affiliated with academic medical centers.

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Based on the evidence and independent clinical input, the clinical input supports that the following indications provide a clinically meaningful improvement in the 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 right ventricular outflow tract (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).

### 2011 Input

In response to requests, input was received from 6 academic medical centers while this policy was under review in 2011. Overall response to whether TPVI was investigational was mixed, with 2 of 5 reviewers agreeing with the investigational status, and 3 reviewers indicating partial support. Most reviewers (4/5) indicated that there is a subpopulation of patients who are high risk for surgery or who are not candidates for surgery, for whom there are no other available options. These reviewers suggested TPVI was a viable alternative that offered potential benefit for these patients.

### Practice Guidelines and Position Statements

#### **Society for Cardiovascular Angiography and Interventions et al**

The Society for Cardiovascular Angiography and Interventions, American Association for Thoracic Surgery, American College of Cardiology (ACC), and the Society of Thoracic Surgeons (2015) published a consensus-based report on operator and institutional requirements for transcatheter pulmonary valve implantation (TPVI). Recommendations to qualify for a TPVI program included 150 catheterizations per year, association with a surgical program, submission of all cases to a national registry, and, for patients, 80% freedom from reintervention at 1 year.

#### **American Heart Association and American College of Cardiology**

The 2014 American Heart Association (AHA) and ACC guidelines on the management of patients with valvular disease and the 2017 AHA and ACC focused update do not make specific recommendations on the treatment of primary pulmonary valve disease (stenosis or regurgitation),

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but instead referred to the 2008 guidelines for the management of adults with congenital heart disease.

In 2008, the AHA and ACC (in collaboration with other medical societies) issued guidelines for the management of adults with congenital heart disease. For patients with isolated valvular pulmonary stenosis, the guidelines make recommendations on balloon valvulotomy or surgical intervention; however, TPVI was not addressed. In 2015, an AHA scientific statement on congenital heart disease in older adults was published and meant to complement the 2008 ACC and AHA guidelines for adults with congestive heart disease. The intent was to outline the natural history, ramifications of childhood repair, and late initial diagnosis of congestive heart disease in older adults. The statement commented on the emerging use of the currently available transcatheter valve repair devices for both pulmonary stenosis and pulmonary valve regurgitation primarily after repair of tetralogy of Fallot. There was a specific comment that contemporary morbidity, mortality, and durability of surgical pulmonary valve regurgitation are unknown and, therefore, no contemporaneous benchmark against which to compare transcatheter valve implantation.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. FDA-approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01186692 <sup>a</sup>	Melody <sup>®</sup> ‡ Implantation of the Medtronic Melody Transcatheter Pulmonary Valve (TPV) in Patients	131	Jul 2017 (ongoing)

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	With Dysfunctional Right Ventricular Outflow Tract (RVOT) Conduits: A Post-Market Approval Study		
NCT00676689 <sup>a</sup>	Implantation of the SAPIEN Transcatheter Heart Valve (THV) in the Pulmonic Position	70	Nov 2019
NCT00740870 <sup>a</sup>	Implantation of the Medtronic Melody Transcatheter Pulmonary Valve in Patients With Dysfunctional RVOT Conduits: A Feasibility Study	150	Jan 2020
NCT02744677 <sup>a</sup>	Congenital Multicenter Trial of Pulmonic Valve Dysfunction Studying the SAPIEN 3 interventional THV	58	Dec 2022
NCT02979587	The Medtronic Harmony <sup>TM</sup> ‡ Transcatheter Pulmonary Valve Clinical Study	40	Dec 2023
NCT02987387 <sup>a</sup>	New Enrollment SAPIEN XT Post-Approval Study	191	Jan 2024

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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# Louisiana

## Transcatheter Pulmonary Valve Implantation

Policy # 00576

Original Effective Date: 10/18/2017

Current Effective Date: 09/14/2020

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### **Policy History**

Original Effective Date: 10/18/2017

Current Effective Date: 09/14/2020

- |            |  |
|------------|--|
| 10/05/2017 | Medical Policy Committee review  |
| 10/18/2017 | Medical Policy Implementation Committee approval. New policy.  |
| 08/09/2018 | Medical Policy Committee review  |
| 08/15/2018 | Medical Policy Implementation Committee approval. Clinical input was obtained and the first policy statement changed to: Transcatheter pulmonary valve implantation is considered medically necessary for patients with congenital heart |

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disease and current right ventricular outflow tract obstruction or regurgitation including the specified indications.

01/01/2019 Coding update

08/01/2019 Medical Policy Committee review

08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/06/2020 Medical Policy Committee review

08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2021

### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	33440, 33477
HCPCS	No codes
ICD-10 Diagnosis	I97.0, I97.110, I97.130, I97.190, Q20.5, Q21.3, Q22.0-Q22.3, T82.01XA-T82.09XS, T82.221A-T82.228S, Z95.2-Z95.4

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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