Transcatheter Pulmonary Valve Implantation

Policy # 00576
Original Effective Date: 10/18/2017
Current Effective Date: 10/14/2024

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.

Note: Transcatheter Aortic-Valve Implantation for Aortic Stenosis is addressed separately in medical policy 00406.

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 with a Food and Drug Administration-approved valve for individuals 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 valve conduit. These repairs are prone to development of pulmonary stenosis or regurgitation over long periods of follow-up. Individuals living with congenital heart disease also face disparities in social determinants of health and the inability to obtain quality lifelong care for their condition which can contribute to inequities in morbidity and mortality.

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

Treatment options for pulmonary stenosis are open surgery with valve replacement, balloon dilatation, or percutaneous stenting. The established 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.

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. 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) (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®‡ Transcatheter Pulmonary Valve (TPV)	Medtronic	Jan 2010	H080002 (HDE)	Pulmonary valve replacement for pediatric and adult individuals with a dysfunctional, noncompliant RVOT conduit
Melody®‡ TPV	Medtronic	Jan 2015	P140017	Pulmonary valve replacement for pediatric and adult individuals with a dysfunctional, noncompliant RVOT conduit
Melody®‡ TPV	Medtronic	Feb 2017	P140017/S005	Valve-in-valve for individuals 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 individuals with a dysfunctional, noncompliant RVOT conduit
Harmony™‡ TPV	Medtronic	Mar 2021	P200046	Pulmonary valve for pediatric and adult individuals with severe pulmonary regurgitation

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

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) was approved by FDA in 2016 "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).

The Harmony™‡ Transcatheter Pulmonary Valve (Medtronic) received breakthrough technology status in 2019 and PMA in 2021. This device is indicated "for use in pediatric and adult patients with severe pulmonary regurgitation (determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement."

FDA product code: NPV

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 who has previously undergone RVOT surgery are additional indications. Patients with prior congenital heart disease repair are at risk of needing repeated reconstruction procedures.

Summary of Evidence

For individuals who have a history of congenital heart disease and current right ventricular outflow tract (RVOT) obstruction who receive transcatheter pulmonary valve implementation (TPVI) with a U.S. Food and Drug Administration (FDA) approved device and indication, the evidence includes a systematic review of retrospective comparative studies, prospective, interventional, noncomparative studies, and a multicenter registry of 2476 individuals who underwent TPV replacement with a Melody (82%) or Sapien (18%) valve between July 2005 and March 2020. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. Overall, the evidence suggests that TPVI is associated with high rates of short-term technical success and improvements in heart failure-related symptoms and hemodynamic parameters. Most valves have demonstrated competent functioning by Doppler echocardiography at 6- to 12-month follow-ups. 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 8 years post-procedure have suggested that the functional and hemodynamic improvements are durable. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a history of congenital heart disease 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 that the technology results in an improvement in the net health outcome.

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

Clinical input was sought to help determine whether the use of transcatheter pulmonary valve implantation (TPVI) for individuals with congenital heart disease and current right ventricular outflow tract (RVOT) obstruction or regurgitation would provide a clinically meaningful improvement in the net health outcome and whether its use is consistent with generally accepted medical practice. In response to requests, clinical input on the use of 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.

Clinical input was provided by the following specialty societies:

- American College of Cardiology (ACC) and Society for Cardiovascular Angiography and Interventions (SCAI)[a]

[a] Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent.

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 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).

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Society for Cardiovascular Angiography and Interventions and the Adult Congenital Heart Association
In 2020, the Society for Cardiovascular Angiography and Interventions and the Adult Congenital Heart Association published a position statement on operator and institutional recommendations for TPVI. Included were recommendations for interventional training, practicing physician competency, ongoing education and training, and institutional and team requirements.

American College of Cardiology, American Heart Association, et al
In 2018, the American College of Cardiology and American Heart Association and 6 other societies published comprehensive guidelines on the management of patients with congenital heart disease. Included are recommendations for treatment of pulmonary stenosis, pulmonary regurgitation and tetralogy of Fallot (Table 2).

Table 2. ACC/AHA Guidelines on the Management of Patients with Tetralogy of Fallot

Recommendation	SOR	LOE
"Pulmonary valve replacement (surgical or percutaneous) for relief of symptoms is recommended for patients with repaired TOF and moderate or greater PR with cardiovascular symptoms not otherwise explained."	Strong	B-NR
"Pulmonary valve replacement (surgical or percutaneous) is reasonable for preservation of ventricular size and function in asymptomatic patients with repaired TOF and ventricular enlargement or dysfunction and moderate or greater PR."	Moderate	B-NR
"Surgical pulmonary valve replacement may be reasonable for adults with repaired TOF and moderate or greater PR with other lesions requiring surgical interventions."	Weak	C-EO
"Pulmonary valve replacement, in addition to arrhythmia management, may be considered for adults with repaired TOF and moderate or greater PR and ventricular tachyarrhythmia."	Weak	C-EO

ACC/AHA: American College of Cardiology/American Heart Association; B-NR: Non-randomized (moderate quality evidence); C-EO: consensus of expert opinion; LOE: level of evidence, PR: pulmonary regurgitation; SOR: strength of recommendation; TOF: tetralogy of Fallot

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02744677[a]	Congenital Multicenter Trial of Pulmonic valve Dysfunction Studying the SAPIEN 3 interventional THV (COMPASSION S3)	108	Jun 2031
NCT02979587[a]	The Medtronic Harmony™‡ Transcatheter Pulmonary Valve Clinical Study	86	Feb 2031
NCT02987387[a]	New Enrollment SAPIEN XT Post-Approval Study (COMPASSION XT PAS)	57	Sep 2025
NCT04860765[a]	Congenital Multicenter Trial of Pulmonic Valve Dysfunction Studying the SAPIEN 3 Interventional THV Post-Approval Study	150	Aug 2030
NCT05077774[a]	Harmony TPV Post-Approval Study (Harmony PAS2)	150	Mar 2035

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Policy History

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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 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

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	33477
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*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 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;

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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.