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MEDICAL POLICY – 7.01.131

Transcatheter Pulmonary Valve Implantation

BCBSA Ref. Policy:	7.01.131	
Effective Date:	Sept. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Aug. 12, 2024	7.01.132 Transcatheter Aortic-Valve Implantation for Aortic Stenosis
Replaces:	N/A	

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POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
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Introduction

Congenital heart disease is a term that means a person was born with heart problems. These difficulties affect the heart's function and structure. Congenital heart disease can range from mild, which may not need treatment, to severe, which often does. One congenital heart defect is known as right ventricular outflow tract (RVOT) dysfunction. Essentially, it's a problem with how the blood flows as it leaves the heart and goes to the lungs. Repairing it requires reconstructing certain areas of the heart and placing a tube (conduit) to allow the blood to flow correctly. Over a long period of time the conduit can become narrowed or a specific valve can become leaky. A second valve replacement surgery may be needed in this situation. This second surgery is usually done as an open surgery. However, surgery using a long, thin tube (a heart catheter) instead of open heart surgery can be done in certain situations. This policy describes when an additional RVOT surgery using a catheter may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Transcatheter pulmonary valve implantation (TPVI)	**Transcatheter pulmonary valve implantation (TPVI) with a Food and Drug Administration-approved valve is considered medically necessary for individuals with congenital heart disease (CHD) 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 **OR** • Individuals with native or patched RVOT with at least moderate pulmonic regurgitation **OR** • 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.**

Documentation Requirements
The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition • History and physical examination documenting the severity of the condition • Right ventricular outflow tract (RVOT) gradient • Pulmonic regurgitation (if present)

Coding

Code	Description
CPT	
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

Description

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 an individual with congenital heart disease (CHD) who has previously undergone RVOT surgery are additional indications. Individuals with prior CHD repair are at risk of needing repeated reconstruction procedures.

Background

Congenital Heart Disease

CHD, 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 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. Individuals living with CHD 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.[1]

Because individuals with surgically corrected CHD 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.[2]

Treatment

Treatment options for pulmonary stenosis are open surgery with valve replacement, balloon dilatation, or percutaneous stenting.[2] 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.[3]

Summary of Evidence

For individuals who have a history of CHD and current RVOT obstruction who receive TPVI with a US 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 2,476 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 morbidity and mortality. 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 individuals; however, most stent fractures did not require reintervention. Studies with follow-up extending to a maximum of eight years postprocedure 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 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 morbidity and mortality. 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 individuals 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. 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	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

Clinical Input Received 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 TPVI for individuals with CHD and current 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 two 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

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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.[28] 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 six other societies published comprehensive guidelines on the management of individuals with CHD.[29] 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

Recommendation	SOR	LOE
"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, SOR: strength of recommendation; TOF: tetralogy of Fallot; PR: pulmonary regurgitation

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Devices for TPVI were initially cleared from marketing by the US 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 (see **Table 3**).

Table 3. 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

Device	Manufacturer	Date Approved	PMA No.	Indications
				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
Harmony TPV	Medtronic	Mar 2021	P200046	Pulmonary valve for pediatric and adult patients 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 individuals 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 two 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 individuals 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 individuals with a dysfunctional, noncompliant 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 individuals 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 (i.e., 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 RVOT and are clinically indicated for surgical pulmonary valve replacement."

FDA product code: NPV

References

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History

Date	Comments
01/10/12	New Policy – Policy created with literature search through June 15, 2011; considered medically necessary for patients who are high risk for open surgery and are poor surgical candidates due to multiple prior thoracotomies for open heart surgery. Considered investigational for all other indications. Clinical vetting information added.
09/27/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
01/29/13	Replace policy. Policy updated with literature review, references 4, 5, 13-15, 17 added. Medically necessary statement amended to include “when performed according to FDA-approved indications”.
01/21/14	Replace policy. Policy updated with literature review, references 4, 5, 13-15, 17 added. Medically necessary statement amended to include “when performed according to FDA-approved indications”. Policy updated with literature review through September 30, 2013. References 13, 14, 16, 18, 21 added. No change to policy statement. Remove ICD-9 procedure and diagnosis codes; remove all ICD-10 codes except 02RH4JZ (which specifically applies) – these will not be used for adjudication.
09/23/14	Update Related Policies. Add 2.02.30.
01/28/15	Annual Review. Policy updated with literature review through September 23, 2014. References 13, 16-19, and 26-31 added; others renumbered. Policy statement unchanged.
01/19/16	Coding update. New CPT code 33477, effective 1/1/16, added to policy.
02/01/16	Coding update. Added 93799.
09/01/16	Annual Review, approved August 9, 2016. Policy updated with literature review through April 28, 2016; references 3, 5, 7-8, 16, 19, and 36-37 added. Policy statement unchanged. CPT coding updated.

Date	Comments
12/01/17	Annual Review, approved November 14, 2017.Policy updated with literature review through October 2017. References 42-44 added. Policy statement changed to include specific FDA approved device indications for pulmonary valve regurgitation and stenosis. Removed CPT codes 0262T and 93799.
08/01/18	Annual Review, approved July 10, 2018. Policy updated with literature review through May 2017; references 9. 22, and 43 added. Clinical input was obtained and 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 when specified indications are met.
04/01/19	Minor update, added Documentation Requirements section.
09/01/19	Annual Review, approved August 22, 2019. Policy updated with literature review through April 2019, no references added. Policy statements unchanged.
09/01/20	Annual Review, approved August 4, 2020. Policy updated with literature review through April, 2020, no references added. Policy statements unchanged.
09/01/21	Annual Review, approved August 3, 2021. Policy updated with literature review through May 11, 2021; references added. Policy statements minor revision to specify FDA-approved devices.
09/01/22	Annual Review, approved August 8, 2022. Policy updated with literature review through May 10, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
06/15/23	Updated Related Policies. 7.01.585 is replaced with 7.01.132 Transcatheter Aortic-Valve Implantation for Aortic Stenosis.
09/01/23	Annual Review, approved August 7, 2023. Policy updated with literature review through May 2, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
09/01/24	Annual Review, approved August 12, 2024. Policy updated with literature review through April 18, 2024; reference added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member

benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.