MASSACHUSETTS

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Medical Policy

# Transcatheter Pulmonary Valve Implantation

## Table of Contents



## Policy Number: 403

BCBSA Reference Number: 7.01.131 (For Plan internal use only)
NCD/LCD: N/A

## Related Policies

Transcatheter Aortic Valve Implantation for Aortic Stenosis #392

## Policy

### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Transcatheter pulmonary valve implantation with a Food and Drug Administration-approved valve is considered **MEDICALLY NECESSARY** for individuals with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation including the following indications:

- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation
- Individuals with native or patched RVOT with at least moderate pulmonic regurgitation
- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg), **OR**
- Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

Transcatheter pulmonary valve implantation is considered **INVESTIGATIONAL** for all other indications.

## Prior Authorization Information

**Inpatient**

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

**Outpatient**

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

| | Outpatient |
|---|---|

| | |
|---|---|
| **Commercial Managed Care (HMO and POS)** | Prior authorization is **not required**. |
| **Commercial PPO and Indemnity** | Prior authorization is **not required**. |
| **Medicare HMO Blue℠** | Prior authorization is **not required**. |
| **Medicare PPO Blue℠** | Prior authorization is **not required**. |

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### CPT Codes

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

## Description

**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. [1,]

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.[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

**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 a patient with congenital heart disease who has previously undergone RVOT surgery are additional indications. Individuals 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 RVOT obstruction who receive TPVI with a U.S. Food and Drug Administration (FDA) approved device and indication, the evidence includes a systematic review of retrospective comparative studies and prospective, interventional, noncomparative studies. 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. 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 7 years post-procedure have suggested that the functional and hemodynamic improvements are durable, but a relatively high proportion of individuals (20% to 30%) have required reintervention on the pulmonary valve. Retrospective comparative studies have been reported but are limited by differences in patient characteristics between those who are treated with percutaneous and open heart procedures. The evidence is insufficient 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 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.

**Additional Information**
**2018 Input**
Clinical input was sought to help determine whether the use of transcatheter pulmonary valve implantation for individuals with congenital heart disease 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 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.

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).

## Policy History

| Date | Action |
|---|---|
| 8/2022 | Annual policy review. References added. Minor editorial refinements to policy statements; intent unchanged. |
| 8/2021 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |

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| 8/2020 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 8/2019 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 10/2018 | Annual policy review. Policy criteria revised. Prior authorization information clarified. Effective 10/1/2018. |
| 9/2016 | Annual policy review. FDA approval information updated. References added. 9/1/2016 |
| 7/2016 | Annual policy review. New references added. |
| 1/2016 | Clarified coding information. |
| 12/2014 | Annual policy review. New references added. |
| 2/2014 | Annual policy review. New references added. Clarified coding information. |
| 6/2013 | Annual policy review. No change to policy statement. Effective 6/1/2013. |
| 12/1/2012 | New policy describing ongoing coverage and non-coverage. Effective 12/1/2012. |

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

## References


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