Medical Policy
Transcatheter Pulmonary Valve Implantation

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Policy Number: 403
BCBSA Reference Number: 7.01.131
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 BlueSM and Medicare PPO BlueSM Members

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.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>N/A</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>N/A</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>N/A</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>N/A</td>
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</table>
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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>33477</td>
<td>Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed</td>
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### Description

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.

Because individuals with surgically corrected congenital heart disease repair are living longer 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.¹

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.² 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.

The Melody Transcatheter Pulmonary Valve (TPV) 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 the artificial valve, and then the outer balloon is inflated to position the valve into place.
Summary
Transcatheter pulmonary valve implantation (TPVI) received approval from the U.S. Food and Drug Administration under a humanitarian device exception in January 2010 for patients with previous repair of congenital heart disease (CHD) and right ventricular outflow tract (RVOT) obstruction. Patients with prior CHD repair are at risk of needing repeated reconstruction procedures. TPVI has been proposed as a less invasive alternative to open surgical pulmonary valve replacement or reconstruction for RVOT obstruction.

For individuals who have a history of CHD and current RVOT obstruction who receive TPVI with an FDA-approved device and indication, the evidence includes 1 prospective, interventional, noncomparative study and multiple prospective and retrospective case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity and mortality. Results of the case series indicate that there is a high rate of procedural success and low procedural mortality, although the rates of serious procedural adverse events reported ranges from 3.0% to 7.4%. Most valves demonstrate competent functioning by Doppler echocardiography at 6- to 12-month follow-up, but complications (eg, stent fractures, need for reinterventions) were reported in an 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, most stent fractures have not required reintervention. Studies with follow-up extending to a maximum of 7 years postprocedure have suggested that the functional and hemodynamic improvements are durable, but a relatively high proportion of patients (20%-30%) require reintervention on the pulmonary valve. No comparative studies were identified, and there is no direct evidence that TPVI leads to a reduction in 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 morbidity and mortality. There is currently 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. The published relatively small case series are heterogeneous in terms of the device used and the indications for TPVI. The evidence is insufficient to determine the effects of the technology on health outcomes.

In patients who are not candidates for open surgery or are at high risk for surgery due to other medical comorbidities, alternative treatment options are limited. Clinical vetting 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 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.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>9/2016</td>
<td>BCBSA National medical policy review. FDA approval information updated. References added. 9/1/2016</td>
</tr>
<tr>
<td>7/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>1/2016</td>
<td>Clarified coding information.</td>
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<tr>
<td>12/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>12/1/2012</td>
<td>New policy describing ongoing coverage and non-coverage. Effective 12/1/2012.</td>
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</tbody>
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References


40. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart