Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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<th>Populations</th>
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<th>Comparators</th>
<th>Outcomes</th>
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FDA: U.S. Food and Drug Administration

Description

Transcatheter pulmonary valve implantation (TPVI) received approval from the U.S. Food and Drug Administration (FDA) 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.

Summary of Evidence

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 one 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 six to 12-month follow-up, but complications (e.g., 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 seven years post-procedure 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.

Policy

Transcatheter pulmonary valve implantation, when performed according to Food and Drug Administration–approved indications, is considered medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract 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.

Background

Description of 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 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.

**Description of Technology**

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.

**Regulatory Status**

On January 25, 2010, the Melody® TPV and the Ensemble® Transcatheter Valve Delivery System (Medtronic, Minneapolis, MN) were approved by the FDA under the humanitarian device exemption 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

In 2015, approval of the Melody® device was amended to a premarket approval (PMA) because FDA determined that the device represented a breakthrough technology.² The PMA was based, in part, on two prospective clinical studies, the Melody® TPV Long-term Follow-up Post Approval Study (PAS) and the Melody TPV New Enrollment PAS.

On February 29, 2016, the Edwards Sapien XT™ Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences), composed of a stainless steel frame with bovine pericardial tissue leaflets and available in 23- and 26-mm sizes, was approved by FDA through the PMA process “for use in pediatric and adult patients with a dysfunctional, non-compliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and:

- pulmonary regurgitation ≥ moderate and/or
- mean RVOT gradient ≥ 35 mmHg.”

FDA product code: NPV.

**Related Protocol**

Transcatheter Aortic Valve Implantation for Aortic Stenosis
Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


