Protocol

Transcatheter Pulmonary Valve Implantation

(701131)

Medical Benefit		Effective Date: 10/01/13	Next Review Date: 07/15
Preauthorization	No	Review Dates: 07/12, 07/13, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *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.*

Description

Transcatheter pulmonary valve implantation (TPVI) is an alternative to pulmonary valve replacement by open surgery. It is intended for patients who have previously had a pulmonary valve repair for congenital heart disease, in whom dysfunction of the repaired valve necessitates further intervention.

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 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.

As individuals with prior congenital heart disease repair are living longer into adulthood, the problem of 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 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 up the artificial valve, and then the outer balloon is inflated to position the valve into place.

Regulatory Status

The Melody® transcatheter pulmonary valve and the Ensemble® Transcatheter Valve Delivery System, manufactured by Medtronic Heart Valves, Inc. (Santa Ana, CA), received U.S. Food and Drug Administration (FDA) approval under the Humanitarian Device Exemption (HDE) Program on January 25, 2010. Approval was 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 was equal to or greater than 16 mm in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
  - Regurgitation: ≥ moderate regurgitation, or
  - Stenosis: mean RVOT gradient ≥ 35 mm Hg

Related Protocol

Transcatheter Aortic Valve Implantation for Aortic Stenosis

Policy (Formerly Corporate Medical Guideline)

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.

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.

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