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Medical Policy

Transcatheter Pulmonary Valve Implantation	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Surgery
Original Policy Date: March 30, 2012	**Effective Date:** March 30, 2012

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

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, when dysfunction of the repaired valve necessitates further intervention.

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 valve conduit. These repairs are prone to development of pulmonary stenosis or regurgitation over long periods of follow up. Calcification of the RVOT conduit can lead to pulmonary stenosis, while dilatation from aneurysm can result in pulmonary regurgitation either leads to decreased exercise tolerance, potentially fatal arrhythmias, and/or irreversible right ventricular dysfunction.

Treatment options for pulmonary stenosis are:

- Open surgery with valve replacement
- Balloon dilatation
- Percutaneous stenting.

Interventions for pulmonary regurgitation are primarily surgical, either reconstruction of the RVOT conduit or replacement of the pulmonary valve through open surgery.

Transcatheter pulmonary valve implantation 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 time.

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 the use of cardiopulmonary bypass.

The Melody transcatheter pulmonary valve and the Ensemble Transcatheter Valve Delivery System, manufactured by Medtronic Heart Valves, Inc (Santa Ana, CA), received United States 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
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
    - Regurgitation: >/= moderate regurgitation, or
    - Stenosis: mean RVOT gradient >/= 35 mmHg

Policy

Transcatheter pulmonary valve implantation may be considered **medically necessary** for patients with prior repair of congenital heart disease and right ventricular outflow tract (RVOT)

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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
- Poor surgical candidate due to multiple prior thoracotomies for open heart surgery

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

Policy Guideline

Eligibility criteria for transcatheter pulmonary valve implantation (TPVI) includes a dysfunctional right ventricular outflow tract (RVOT) conduit or a dysfunctional bioprosthetic pulmonary valve, plus evidence of heart failure. Generally defined as:

- Patients with New York Heart Association (NYHA) class I heart failure, a Doppler mean gradient of equal to or greater than 40 mmHg or severe pulmonary regurgitation
- Patients with NYHA class II-IV heart failure, a mean gradient of equal to or greater than 35 mmHg or moderate pulmonary regurgitation

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review

• History and Physical and Consultation report(s) including:
  o All previous surgeries, treatments, and responses pertaining to request
  o New York Heart Association Classification of symptoms
  o Pulmonary valve stenosis severity description
  o Reason for procedure
• Consultation report(s) including cardiovascular interventionalist and cardiothoracic surgeon
• Echocardiogram within last six months
 	
Post Service
• Operative report(s)

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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

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