APPENDIX to Transcatheter Pulmonary Valve Implantation Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity.**

For instances when the indication is **investigational,** you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

The published literature on transcatheter pulmonary valve implantation (TPVI) consists of small case series, which generally report on short term outcomes.

According to two studies (McElhinney et al., 2010) and (Zahn EM et al., 2009) the multicenter United States Melody ™ Transcatheter Pulmonary Valve trial was a prospective uncontrolled trial from five clinical sites designed to study the safety, procedural success, and short term effectiveness of the Melody ™ Transcatheter Pulmonary Valve. This study was designed to follow 150 patients over a five year period. Eligibility criteria included a dysfunctional right ventricular outflow tract (RVOT) conduit or a dysfunctional bioprosthetic pulmonary valve, plus evidence of heart failure:

- **For patients with New York Heart Association (NYHA) class I heart failure**:
    - Doppler mean gradient of equal to or greater than 40 mmHg or severe pulmonary regurgitation was required

- **For patients with NYHA class II-IV heart failure:**
  - Doppler mean gradient of equal to or greater than 35 mmHg or moderate pulmonary regurgitation

These inclusion criteria generally were indications for pulmonary valve replacement. The primary outcomes were defined as:

- Procedural success
- Adverse events from the procedure
- Effectiveness measured by the proportion of patients with acceptable valve function at six months

The most recent publication reported on 136 patients who underwent attempted TPVI (McElhinney DB et al., 2010). A total of 124 out of 136 patients (91.2%) had successful procedural replacement of the pulmonary valve. In 12 patients, replacement was not possible due to anatomic or other intra procedural findings that precluded implantation. One death occurred as a result of the procedure (0.7%), and serious adverse events occurred in 8 out of 136 patients (6%). Adverse events included:

- Coronary artery dissection
- Conduit rupture/tear
- Wide complex tachycardia
- Respiratory failure
- Femoral vein thrombosis
- Perforation of the pulmonary artery

At the six month follow-up time point a total of 94 patients had acceptable valve function, RVOT improvement defined as; mild pulmonary regurgitation or less on echocardiography (present in greater than 90% of patients) and improvement to NYHA class I heart failure (75.5% of patients). Over the course of follow up, stent fractures were diagnosed in 20.2% patients, and 7.3% required implantation of a second valve (Zahn et al., 2010)

The United States Food and Drug Administration (FDA) reviewed results from this trial in 99 patients enrolled between January 2007 and December 2008, and reported more detailed data on complications from the procedure (FDA, 2011). A total of 90 patients were deemed suitable for implantation following catheterization Implantation was successful in 87 out of 90 patients. There was one procedural related death (1.1%). Re-interventions were balloon angioplasty in one patient; repeat implantation of a second TPVI in five patients.

In the FDA analysis 64 patients reached six months of follow up. Of these, 87.5% had acceptable hemodynamic function of the valve by Doppler echocardiography. At six months, approximately 75% of patients were in NYHA class I, and 25% were in NYHA class II. Pulmonary regurgitation that was mild or worse was present in 6.2% of patients.

In response to requests for clinical vetting in 2011, Blue Cross Blue Shield Association (BCBSA) received input from five academic medical centers. Overall response to whether TPVI was investigational was mixed, with two of five reviewers indicating they agree with the investigational status, and three reviewers who indicated it was a split decision. The majority of

reviewers (4/5) indicated in their written response that there was a subpopulation of patients who were high risk for surgery or who were not candidates for surgery, in whom there were no other available options. These reviewers felt that TPVI was a viable alternative that offered potential benefit for these patients (Vezmar M et al., 2010).

Summary

In summary, TPVI received FDA approval under the Humanitarian Device Exception program in January 2010 for patients with previous repair of congenital heart disease and RVOT obstruction. There is currently a lack of high quality evidence evaluating outcomes of this procedure for the indicated population. No randomized controlled trials have been performed, and there are no controlled trials that compare TPVI to available alternatives. The available evidence consists of case series of patients with RVOT dysfunction who require re-intervention.

The results of the case series indicated that there was a high rate of procedural success and low procedural mortality. The rate of serious procedural adverse events reported in these series ranged from 3.0% to 7.4%. At six months to one-year follow-ups, there was evidence that the majority of valves demonstrated competent functioning by Doppler echocardiography, with the majority of patients in NYHA functional class I or II. Complications at six month follow-up, such as stent fractures and the need for re-interventions, were reported by the FDA analysis to occur at rates of 18% and 7%, respectively. There is no direct evidence to demonstrate that TPVI leads to a reduction in future open heart procedures.

In patients who are not candidates for open surgery, or who are at high risk for surgery due to other medical comorbidities, alternative treatment options are limited. Clinical vetting received by BCBSA 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 the evidence on short term success, TPVI can be considered medically necessary for patients who are not candidates for open repair or who are high risk for open repair. For all other indications, TPVI is considered investigational.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the

terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	0262T	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach
HCPC	None	
ICD9 Procedure		
	35.26	Other replacement of pulmonary valve
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

Melody ™ Transcatheter Pulmonary Valve – A device used 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 platinum iridium stent scaffolding. 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.

Ensemble ™ Transcatheter Valve Delivery System – This system is used with the Melody ™ Transcatheter Pulmonary Valve for percutaneous replacement of a dysfunctional pulmonary valve. 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.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

- Melody ™ transcatheter pulmonary valve (Medtronic Heart Valves, Inc.).
- Ensemble ™ Transcatheter Valve Delivery System (Medtronic Heart Valves, Inc.).
- Right ventricular outflow tract (RVOT)

References

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
3/30/2012	New Policy Adoption	Medical Policy Committee

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 policy statement for this policy

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