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| Medical Benefit | | Effective Date: 04/01/19 | Next Review Date: 01/20 |
| Preauthorization | No | Review Dates: 07/12, 07/13, 07/14, 07/15, 01/16, 01/17, 01/18, 01/19 | |

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.

| Populations | Interventions | Comparators | Outcomes |
|---|--|--|---|
| Individuals: <ul style="list-style-type: none"> • With a history of congenital heart disease and current right ventricular outflow tract obstruction | Interventions of interest are: <ul style="list-style-type: none"> • Transcatheter pulmonary valve implantation with an FDA-approved device and indication | Comparators of interest are: <ul style="list-style-type: none"> • Open surgical pulmonary valve replacement or reconstruction | Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related mortality • Treatment-related morbidity |
| Individuals: <ul style="list-style-type: none"> • With a history of congenital heart disease and current right ventricular outflow tract obstruction | Interventions of interest are: <ul style="list-style-type: none"> • Transcatheter pulmonary valve implantation with a non-FDA-approved device or indication | Comparators of interest are: <ul style="list-style-type: none"> • Open surgical pulmonary valve replacement or reconstruction | Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related mortality • Treatment-related morbidity |

FDA: U.S. Food and Drug Administration

DESCRIPTION

Transcatheter pulmonary valve implantation (TPVI) is a less invasive alternative to open surgical pulmonary valve replacement or reconstruction for right ventricular outflow tract (RVOT) obstruction. Percutaneous pulmonary valve replacement may be indicated for congenital pulmonary stenosis. Pulmonary stenosis or regurgitation in a patient with congenital heart disease (CHD) who has previously undergone RVOT surgery are additional indications. Patients with prior CHD repair are at risk of needing repeated reconstruction procedures.

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 prospective, interventional, noncomparative studies, and multiple prospective and retrospective case or cohort series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. Results of the case series have indicated that there is a high rate of procedural success and low procedural mortality, although the rates of serious procedural adverse events reported ranged from 3.0% to 7.4%. Most valves have demonstrated competent functioning by Doppler echocardiography at six- to 12-month follow-ups, but complications (e.g., stent fractures, need for reinterventions) were reported in an U.S. Food and Drug Administration (FDA) analysis 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 did not require reintervention. Studies with follow-up extending to a maximum of seven years postprocedure have suggested that the functional and hemodynamic improvements are durable, but a relatively high proportion of patients (20%-30%) have required reintervention on the pulmonary valve. No comparative studies were identified, and there is no direct evidence that TPVI reduces 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 mortality and morbidity. There is limited evidence on the off-label use of TPVI including the use of a non-FDA-approved valve or use of an approved valve for a non-FDA-approved indication. The published case series enrolled relatively few patients and are heterogeneous regarding devices used and 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 who are at high risk for surgery due to other medical comorbidities, alternative treatment options are limited. Clinical vetting obtained in 2011 indicated near-uniform support for the use of TPVI in both groups of these patients. 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.

Clinical input obtained in 2018 supports that the following indications provide a clinically meaningful improvement in net health outcome and are consistent with generally accepted medical practice.

- Use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Use of TPVI for individuals with native or patched RVOT with at least moderate pulmonic regurgitation;
- Use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
- Use of TPVI for individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

POLICY

Transcatheter pulmonary valve implantation is considered **medically necessary** for patients with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation including the following indications:

- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Individuals with native or patched RVOT with at least moderate pulmonic regurgitation;
- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
- Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

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

BACKGROUND

CONGENITAL HEART 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 using 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 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

Treatment

Interventions for RVOT dysfunction often require numerous repeat 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. The optimal timing of these interventions is not well understood.²

Transcatheter pulmonary valve replacement offers a less invasive treatment option for patients with prior surgery for congenital heart disease and RVOT dysfunction. It is possible that a less invasive valve replacement technique could spare patients from multiple repeat open heart procedures over long periods of follow-up.

REGULATORY STATUS

Devices for transcatheter pulmonary valve implantation were initially cleared from marketing by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process or used off-label until approved by FDA through the premarket approval (PMA) process between 2015 and 2016 (see Table 1).

Table 1. Regulatory Status of Transcatheter Pulmonary Valve Implantation Devices

| Device | Manufacturer | Date Approved | PMA No. | Indications |
|---|--------------|---------------|---------------|--|
| Melody® Transcatheter Pulmonary Valve (TPV) | Medtronic | Jan 2010 | H080002 (HDE) | Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit |
| Melody TPV | Medtronic | Jan 2015 | P140017 | Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT |

| Device | Manufacturer | Date Approved | PMA No. | Indications |
|--|----------------------|---------------|--------------|--|
| Melody TPV | Medtronic | Feb 2017 | P140017/S005 | conduit Valve-in-valve for patients with a dysfunctional surgical bioprosthetic pulmonary valve |
| SAPIEN XT™ Transcatheter Heart Valve (pulmonic) | Edwards Lifesciences | Feb 2016 | P130009/S037 | Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit |

HDE: humanitarian device exemption; PMA: premarket approval; RVOT: right ventricular outflow tract.

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 are 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 a beating heart without the 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.

In January 2010, the Melody® TPV and the Ensemble® Transcatheter Valve Delivery System (Medtronic) were approved by FDA under the HDE 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 or greater.

On January 27, 2015, approval of the Melody® system was amended to a PMA because FDA determined that the device represented a breakthrough technology.³ The PMA was based, in part, on two prospective clinical studies, the Melody TPV Long-term Follow-up Post Approval Study and the Melody TPV New Enrollment Post Approval Study.

On February 24, 2017, approval of the Melody® system was expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve).

The Edwards SAPIEN XT™ Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) is composed of a stainless steel frame with bovine pericardial tissue leaflets and available in 23- and 26-mm sizes. It includes a delivery accessories system. On February 29, 2016, it was approved by FDA as a supplement “for use in pediatric and adult patients with a dysfunctional, noncompliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and:

- pulmonary regurgitation \geq moderate and/or
- mean RVOT gradient \geq 35 mm Hg.”

The approval for the pulmonic valve indication is a supplement to the 2014 PMA for use of the Edwards SAPIEN XT™ Transcatheter Heart Valve System for relief of aortic stenosis in patients with symptomatic heart disease

due to severe native calcific aortic stenosis and who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons operative risk score $\geq 8\%$ or at a $\geq 15\%$ risk of mortality at 30 days).

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.**

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

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