Clinical Policy Title: Melody™ transcatheter pulmonary valve (TPV) replacement

Clinical Policy Number: 04.03.08

Effective Date: January 1, 2017
Initial Review Date: October 19, 2016
Most Recent Review Date: October 19, 2016
Next Review Date: October 2017

Policy contains:
- Transcatheter pulmonary valve
- Melody™ valve

Related policies:
CP# 04.03.01 Transcatheter aortic and mitral valve replacement and repair
CP# 04.02.06 Heart valve transplant

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of Melody™ TPV as an adjunct to surgery in the management of pediatric and adult members for valve replacement to be clinically proven and, therefore, medically necessary for the following clinical conditions:

- Existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted, and
- Dysfunctional RVOT conduit with a clinical indication for intervention, and:
  - regurgitation: ≥ moderate regurgitation, and/or
  - stenosis: mean RVOT gradient ≥ 35 mmHg.

Limitations:

All other uses of Melody™ TPV are not medically necessary.
**Alternative covered services:**

Members should fully discuss alternatives with his or her physician to select the method that best meets expectations and lifestyle.

**Background**

There are many types of congenital heart defects. Some are simple, such as atrial septal defect (ASD), ventricular septal defect (VSD), and patent ductus arteriosus (PDA). Simple congenital heart defects also can involve the heart's valves. Heart valves can have defects that require intervention such as stenosis, atresia, and regurgitation.

The most common valve defect is pulmonary valve stenosis, which is a narrowing of the pulmonary valve. This valve allows blood to flow from the right ventricle into the pulmonary artery. The blood then travels to the lungs to pick up oxygen. Pulmonary valve stenosis can range from mild to severe. Most children who have this defect have no signs or symptoms other than a heart murmur. Treatment isn't needed if the stenosis is mild.

Other heart defects are more complex. They include combinations of simple defects, problems with the location of blood vessels leading to and from the heart, and more serious problems with how the heart develops. The most common complex heart defect is Tetralogy of Fallot, which is a combination of four defects which can include pulmonary valve stenosis.

Patients born with heart defects typically need several surgeries during their lifetimes to correct their heart problems. The use of the Melody TPV will delay the time when a patient needs additional open heart surgery. It can also reduce the total number of open heart surgeries a patient needs.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved the Melody™ TPV device by Medtronic Inc. on January 27, 2015. According to the approval letter, models Melody™ Transcatheter Pulmonary Valve, models PB1016 and PB1018 Ensemble™ Transcatheter Valve Delivery System, models NU1018, NU1020, and NU1022 were approved (FDA 2015).

Transcatheter pulmonary valve (TPV) is an artificial heart valve made from the jugular vein valve of a cow that is sewn into a small metal frame. The Medtronic Ensemble Transcatheter Valve Delivery System is a thin, hollow, and long tube (catheter) that delivers the Melody TPV into the heart without open heart surgery while the heart is beating.

The Melody TPV is first compressed onto a balloon at the tip of the delivery catheter. Through a small incision typically in the groin, the Melody TPV is pushed through a vein to the failing pulmonary heart valve. The small balloon is then inflated to open up the Melody TPV and the catheter is removed from the body. The Melody TPV immediately becomes the new pulmonary heart valve.
Dr. Christopher J. Petit of Children’s Healthcare of Atlanta, Georgia, writes, “In contrast to reports of surgically implanted pulmonary valves, this study indicates that the Melody valve remains non-stenotic and non-regurgitant up to seven years after implantation.” He further stated, “The ramifications of such promising midterm results are important.” The study “allows the clinician to more confidently counsel families when considering [transcatheter pulmonary valve replacement] and likewise gives our surgical colleagues good reason to implant conduits and valve prostheses compatible with future Melody utilization” (Petit 2015).

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 25, 2016. Search terms were: “Melody TPV; failed RV to PA conduit; pulmonary valve; transcatheter pulmonary valve” MESH.

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

N/A

**Policy updates:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
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<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| McElhinney DB (2013) | **Key points:**  
| The Melody® valve and Ensemble® delivery system for transcatheter pulmonary valve replacement. | - The Melody® TPV is a percutaneous valve system designed for the treatment of obstruction and/or regurgitation of prosthetic conduits placed between the right ventricle and pulmonary arteries in patients with congenital heart disease. In 2000, Melody TPV became the first transcatheter valve implanted in a human; in 2006 it became the first transcatheter valve commercially available anywhere in the world; and in 2010 it was launched as the first commercially available transcatheter valve in the United States. In this review, we present the clinical background against which the Melody valve was developed and implemented, introduce the rationale for and challenges of transcatheter valve technology for this population, outline the history and technical details of its development and use, and summarize currently available data concerning the performance of the device. |
| Armstrong A K et al. (2014) | **Key points:**  
| One-Year Follow-Up of the Melody Transcatheter Pulmonary Valve Multicenter Post-Approval Study | - Cardiac catheterization was performed in 120 patients for potential implantation of the Melody TPV; of these, 100 patients were implanted, with a 98% procedural success rate. There were no procedure-related deaths. Acceptable hemodynamic function at 6 months was achieved in 96.7% of patients with evaluable data (87.9% of the entire implanted cohort), with results maintained through one year.  
- No patient had moderate or severe pulmonary regurgitation after implantation. No patient required catheter reintervention in the first year after implantation, and two patients required reoperation for conduit replacement. The rate of freedom from TPV dysfunction was 96.9% at one year.  
- This first prospective, real-world experience with the Melody TPV in the United States demonstrates continued high procedural success, excellent short-term TPV function, and low reintervention and reoperation rates at one year (Melody Transcatheter Pulmonary Valve Post-Approval Study; NCT01186692). |
| Khambadkone S et al. (2005) | **Key point:**  
| Percutaneous pulmonary valve implantation in humans: results in 59 consecutive patients. | - Right ventricular outflow tract (RVOT) reconstruction with valved conduits in infancy and childhood leads to reintervention for pulmonary regurgitation and stenosis in later life.  
- Patients with pulmonary regurgitation with or without stenosis after repair of congenital heart disease had percutaneous pulmonary valve implantation (PPVI). Mortality, hemodynamic improvement, freedom from explantation, and subjective and objective changes in exercise tolerance were end points. PPVI was performed successfully in 58 patients, 32 male, with a median age of 16 years and median weight of 56 kg. The majority had a variant of tetralogy of Fallot (n=36), or transposition of the great arteries, ventricular septal defect with pulmonary stenosis (n=8).  
- PPVI is feasible at low risk, with quantifiable improvement in MRI-defined ventricular parameters and pulmonary regurgitation, and results in subjective and objective improvement in exercise capacity. |

**Glossary**

**Pulmonary regurgitation (PR), also called pulmonic regurgitation** — A leaky pulmonary valve. This valve helps control the flow of blood passing from the heart to the lungs. A leaky pulmonary valve allows blood to flow back into the heart chamber before it gets to the lungs for oxygen.
**Pulmonary stenosis (PS)** — A condition caused by a narrowing of the pulmonary valve opening. Pulmonary stenosis restricts blood flow from the lower right chamber (called the ventricle) to the pulmonary arteries, which delivers blood to the lungs. It is most commonly the result of a congenital heart defect. However, rarely PS can develop as a result of infections like rheumatic fever or carcinoid syndrome.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


Clinical trials:

Searched clinicaltrials.gov on August 28, 9, 2016 using terms transcatheter pulmonary valve, melody valve | Open Studies. 11 studies found, three relevant.


CMS National Coverage Determinations (NCDs):
No NCDs identified as of the writing of this policy.
Local Coverage Determinations (LCDs):

Services That Are Not Reasonable and Necessary (L35094) Revision Effective Date on or after 07/01/2016.

Category III code 0262T (Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach) has been denied as not reasonable and necessary. (Position reaffirmed upon reconsideration.) CPT code 33477 (transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed) is replacing Category III code 0262T as non-covered.


Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
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<tbody>
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<td>33477</td>
<td>Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed</td>
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<tr>
<td>I37.0</td>
<td>Nonrheumatic pulmonary valve stenosis</td>
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<td>I37.1</td>
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<td>I37.2</td>
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