Melody™ transcatheter pulmonary valve replacement

Clinical Policy ID: CCP.1264

Recent review date: 11/2023

Next review date: 3/2025

Policy contains: Melody; pulmonary valve insufficiency; right ventricular outflow tract; transcatheter pulmonary valve replacement.

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Coverage policy

The Melody™ transcatheter pulmonary valve (Medtronic Inc., Mounds View, Minnesota) is clinically proven and, therefore, may be medically necessary as an adjunct to surgery in pediatric and adult members for either of the following clinical indications (Stout, 2019; U.S. Food and Drug Administration, 2015):

- Existence of a full (circumferential) right ventricular outflow tract conduit ≥ 16 mm in diameter when originally implanted.
- Dysfunctional right ventricular outflow tract conduit with a clinical indication for intervention, and either:
  - Regurgitation: ≥ moderate regurgitation.
  - Stenosis: mean right ventricular outflow tract gradient ≥ 35 mmHg.

Limitations

All other uses of the Melody transcatheter pulmonary valve are not medically necessary.

Alternative covered services

Surgical pulmonary valve repair or implantation.

Background

Congenital heart defects are the most common type of birth defect, affecting eight out of every 1,000 newborns. They can affect the interior septa, valves, and blood vessels to and from the heart. Common examples of these include but are not limited, to atrial and ventricular septal defects, patent ductus arteriosis, pulmonary stenosis, coarctation of the aorta, transposition of the great vessels and tetrology of fallot (a combination of four defects). The defects range from simple to life threatening and patients can become symptomatic at any time (National Heart, Lung, and Blood Institute, 2022). About 2.4 million adults are living with these conditions (American Heart Association, 2023).

Pulmonary valve stenosis is a common birth defect that involves narrowing of the pulmonary valve opening, affecting transport of deoxygenated blood from the right ventricle into the pulmonary artery, that connects the heart to the lungs. The right ventricular outflow tract is where blood passes to enter the great arteries. It is an important anatomical feature in many corrective surgeries for congenital heart defects, as dilation of this region can cause pulmonary valve insufficiency (National Heart, Lung, and Blood Institute, 2022).

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 and often require no treatment. More severe or complex cases may require open-heart surgery or a heart transplant. Surgical repair is effective in the short term, but valves and conduits have limited durability. Calcification and scar formation can lead to right ventricular outflow tract dysfunction, which, when severe, results in a blocked or regurgitant pulmonary valve. Percutaneous catheter-based procedures have emerged in the past 20 years and are often the preferred way to repair many simple heart defects (National Heart, Lung, and Blood Institute, 2022).

Melody transcatheter pulmonary valve

The Melody transcatheter pulmonary valve is made from a bovine jugular vein valve sewn into a small metal frame (Medtronic Inc., 2021). The Medtronic Ensemble™ Transcatheter Valve Delivery System (Medtronic Inc., Mounds View, Minnesota) is a thin, hollow, and long catheter that percutaneously delivers the Melody transcatheter pulmonary valve via a balloon catheter into the heart while the heart is beating. The small balloon is then inflated to open up the Melody valve, and the catheter is removed from the body. The Melody valve immediately becomes the new pulmonary heart valve.

The U.S. Food and Drug Administration (2015) approved the Melody transcatheter pulmonary valve models PB1016 and PB1018 and Ensemble Transcatheter Valve Delivery System models NU1018, NU1020, and NU1022 for the following uses:

- Existence of a full (circumferential) right ventricular outflow tract conduit ≥ 16 mm in diameter when originally implanted.
  Dysfunctional right ventricular outflow tract conduit with a clinical indication for intervention, and either at least moderate regurgitation or a mean right ventricular outflow tract gradient ≥ 35 mmHg.

The purported benefits of the Melody transcatheter pulmonary valve are minimal invasiveness and a potential reduction in the risks of bleeding and infection. It may delay the time when a patient needs additional open-heart surgery and reduce the total number of open heart surgeries a patient needs.

Findings

A systematic review analyzed 12 observational studies (n = 677 patients), including 10 studies of the Melody valve, implanted for regurgitation, stenosis, or both (Virk, 2015). No studies directly compared percutaneous procedure to surgery. The evidence suggests that percutaneous pulmonary valve implantation offers an acceptable mortality risk and a relatively low incidence of major procedural complications. The most common

complications were stent fracture and infective endocarditis. There are no known contraindications to the Melody transcatheter pulmonary valve.

Several factors likely contribute to variation in outcomes which may include right ventricular outflow tract etiology and valve pathology, operator experience, and procedure protocol. Others may correlate with improved outcomes such as: pre-procedural stenting of the right ventricular outflow tract; valve-conduit size matching using pre-procedural right ventricular outflow tract measurement; compliance with antibiotic prophylaxis; compliance with anti-platelet therapy; and adequate dental hygiene. Test angioplasty might be indicated to detect pre-existing coronary artery compression, which can lead to a fatal outcome.

Percutaneous pulmonary valve implantation has a learning curve, and protocols that improve outcomes are still being developed. Long-term patient survival, valve durability, and effectiveness in postponing surgery are unclear. The American Heart Association recognizes transcatheter pulmonary valves as an emerging treatment option, but lack of outcome data on surgical pulmonary valve replacement prevents a comparison of outcomes to transcatheter pulmonary valves; these valves are only suitable for patients with non-native right ventricular outflow tracts (Bhatt, 2015).

In 2017, we added one new systematic review and meta-analysis (Chatterjee, 2017) and one post-marketing surveillance study based on adverse event data reported to the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database (Hill, 2017). Chatterjee (2017) included 19 studies of 1,044 patients undergoing transcatheter valve replacement, 942 of whom received Melody. Low rates of conduit rupture (4.1%), coronary complications (1.3%), reintervention (4.4 per 100 person-years), and endocarditis (1.4 per 100 person-years) were reported.

The new information suggests improvement in long-term outcomes, particularly reduced re-intervention rates, which are associated with procedural experience and widespread adoption of pre-stenting in patients with failing pulmonary conduits or dysfunctional surgical bioprosthetic valves. The new information confirms previous findings and warrants no policy changes.

In 2018, we added one systematic review (Abdelghani, 2018), two retrospective chart reviews comparing patient characteristics and outcomes of transcatheter and surgical pulmonary valve replacement (Li, 2018; Zablah, 2017), and one updated evidence-based guideline (Stout, 2018, updated to 2019). The American College of Cardiology/American Heart Association guideline lists the following indications for the Melody valve in adults with congenital heart disease (Stout, 2019):

- Right ventricle-to-pulmonary artery conduit and moderate or greater pulmonary regurgitation or moderate or greater stenosis with reduced functional capacity or arrhythmia.
- Asymptomatic adults with right ventricle-to-pulmonary artery conduit and severe stenosis or severe regurgitation with reduced right ventricular ejection fraction or right ventricular dilation.

While the incidence of infective endocarditis continues to be of concern in Melody valve recipients, the condition can be managed medically, especially in those with streptococcal infection and no right ventricular outflow tract obstruction (Abdelghani, 2018). Comparisons of patient characteristics and outcomes of transcutaneous and surgical pulmonary valve replacement procedures suggest that both procedures can effectively improve right ventricular volume despite having differences in baseline and referral characteristics (Li, 2018; Zablah, 2017). No policy changes are warranted. The policy ID was changed from CP# 04.03.08 to CCP.1264.

In 2019, we added studies that confirm infective endocarditis as an important adverse outcome after Melody transcatheter valve replacement in patients with congenital anomalies involving the right ventricular outflow tract, including:

> Of 309 patients, 46 developed endocarditis within five years, but 89% had freedom from endocarditis at the end of the study period (McElhinney, 2018).

In 42 centers (n = 845), patients followed for a median of 5.9 years had an annual endocarditis incidence rate of 2.3%; nine deaths were recorded in the study group (Nordmeyer, 2019).

No policy changes are warranted.

In 2020, we added one multisite cohort study (Armstrong, 2019), and two systematic reviews and meta-analyses (Rebeiro, 2020; Zhou, 2019) that confirm previous findings and warrant no policy changes.

In 2021, we updated the references and found no new relevant literature to add to the policy.

In 2022, we added a long-term follow up study from 2007 to 2020 (n = 149), of the Melody TPV valve. The primary outcomes at 10 years demonstrated high rates of freedom from mortality (90%); reintervention (60%); reoperation (79%), and implant related endocarditis (81%) (Jones, 2022).

In 2023, we added a systematic review/meta-analysis of 22 studies comparing pulmonary valve transplant patients using SAPIEN (n = 572) versus Melody (n = 1,395) valves. Pooled endocarditis incidence was significantly lower for Sapien patients (2.1% versus 8.5%, *P* =.019). Meta-regression was used to account for differences in length of follow-up between the two groups (Balakrishna, 2023).

We also added a comparison of SAPIEN and Melody long-term outcomes. Secondary pulmonary valve replacement freedom rates were higher for SAPIEN patients at five years (94.3% versus 78.1%) and 10 years (82.2% versus 50.4%) (Houeijeh, 2023).

References

On August 28, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Heart defects, congenital” (MeSH), “Melody transcatheter pulmonary valve,” “pulmonary valve,” and “transcatheter pulmonary valve.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

9/2016: initial review date and clinical policy effective date: 1/2017

11/2017: Policy references updated.

11/2018: Policy references updated. Medicare coverage updated. Policy ID changed.

11/2019: Policy references updated.

11/2020: Policy references updated. Medicare coverage removed.

11/2021: Policy references updated.

11/2022: Policy references updated.

11/2023: Policy references updated.