Melody™ transcatheter pulmonary valve replacement

Clinical Policy ID: CCP.1264

Recent review date: 11/2024

Next review date: 3/2026

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

AmeriHealth Caritas Florida has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Florida 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, on a case by case basis, by AmeriHealth Caritas Florida 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. AmeriHealth Caritas Florida 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. AmeriHealth Caritas Florida clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Florida will update its clinical policies as necessary. AmeriHealth Caritas Florida clinical policies are not guarantees of payment.

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 tetralogy 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).

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

Guidelines

The American College of Cardiology/American Heart Association guideline lists the following indications for percutaneous pulmonary valve replacement (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.

Evidence reviews

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.

Infective endocarditis is a rare but life-threatening condition with potentially long-lasting effects. The most common microorganism affecting the valves is Staphylococcus aureus. The literature is imprecise with regard to the incidence of infective endocarditis. General trends show a higher risk with the Melody valve than with other valves used for pulmonary valve replacement or with a surgical approach, although the surgical approach is associated with more complications. Prior history of infective endocarditis and multiple implants may increase the risk of infective endocarditis. Other risk factors such as gender, balloon post-dilation, smaller right ventricular outflow tract, conduits, stenotic lesions, discontinuation of antiplatelet or anticoagulant prophylaxis, dental hygiene, or non-cardiac surgery after transcatheter pulmonary valve replacement have been reported (Slouha, 2023).

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. Results suggest 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.

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. In a long-term follow up study from 2007 to 2020 of 149 Melody valve recipients, primary outcomes at 10 years demonstrated high rates of freedom from mortality (90%), reintervention (60%), reoperation (79%), and implant-related endocarditis (81%) (Jones, 2022). A comparison of SAPIEN and Melody long-term outcomes found 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).

In 2017, we updated the references and made no policy changes.

In 2018, we updated the references. No policy changes are warranted. The policy ID was changed from CP# 04.03.08 to CCP.1264.

In 2019, we updated the references and made no policy changes.

In 2020, we updated the references and made no policy changes.

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

In 2023, we updated the references made no policy changes.

In 2024, we added and updated the references and made no policy changes.

References

On September 17, 2024, 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.

Chatterjee A, Bajaj NS, McMahon WS, et al. Transcatheter pulmonary valve implantation: A comprehensive systematic review and meta-analyses of observational studies. *J Am Heart Assoc*. 2017;6(8):e006432. Doi: 10.1161/JAHA.117.006432.

Houeijeh A, Batteux C, Karsenty C, et al. Long-term outcomes of transcatheter pulmonary valve implantation with Melody and SAPIEN valves. *Int J Cardiol*. 2023;370:156-166. Doi: 10.1016/j.ijcard.2022.10.141.

Jones TK, McElhinney DB, Vincent JA, et al. Long-term outcomes after Melody transcatheter pulmonary valve replacement in the US investigational device exemption trial. *Circ Cardiovasc Interv*. 2022;15(1):e010852. Doi: 10.1161/CIRCINTERVENTIONS.121.010852.

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National Heart, Lung, and Blood Institute. What are congenital heart defects? https://www.nhlbi.nih.gov/health/congenital-heart-defects. Last updated March 24, 2022.

Slouha E, Johnson LL, Thirunavukarasu A, Al-Geizi H, Clunes LA, Kollias TF. Risk of infective endocarditis post-transcatheter pulmonary valve replacement versus surgical pulmonary valve replacement: A systematic review. *Cureus*. 2023;15(10):e48022. Doi: 10.7759/cureus.48022.

Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC Guideline for the management of adults with congenital heart disease: Executive summary: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2019;73(12):1494-1563. Doi: 10.1016/j.jacc.2018.08.1028.

U.S. Food and Drug Administration. Summary of safety and effectiveness data. Premarket approval application number P140017. http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140017B.pdf. Published January 27, 2015.

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.

11/2024: Policy references updated.