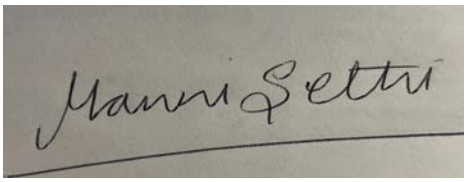
Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 12/22/2022
Policy Number: CCP.1267	**Effective Date:** 1/2017 **Revision Date:** November 1, 2022
Policy Name: Melody™ transcatheter pulmonary valve replacement	
Type of Submission – Check all that apply: ☐ **New Policy** **X Revised Policy*** ☐ **Annual Review – No Revisions** ☐ **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Please see revisions with tracked changes below.	
Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Melody™ transcatheter pulmonary valve replacement

Clinical Policy ID: CCP.1264

Recent review date: 11/2022

Next review date: 3/2024

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

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

Coverage policy

The Melody™ transcatheter pulmonary valve (Medtronic Inc., Mounds View, Minnesota) is clinically proven and, therefore, 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.

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

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 (which is a combination of four defects and very complex). The defects range from simple to life threatening and patients can become symptomatic at any time (National Heart Lung Blood Institute, 2022). More than one million adults are living with these conditions.

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 the portion of the right ventricle through which 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 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 Blood Institute, 2022).

Melody transcatheter pulmonary valve

The Melody transcatheter pulmonary valve is an artificial heart valve made from a bovine jugular vein valve that is 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 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). 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, it 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). These results confirm the need for careful patient selection and risk assessment in determining the optimal candidates for the Melody valve, and no policy changes are warranted. We added a statement of not medically necessary to the Medicare coverage section (Local Coverage Determinations L33777 and L35094). The policy ID was changed from CP# 04.03.08 to CCP.1264.

In 2019, we added three 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 (Groning, 2019; McElhinney, 2018; Nordmeyer, 2019). To place these results in the context of other valve replacement options, one comparative analysis found the risk of infective endocarditis was higher for bovine Contegra grafts (hazard ratio 3.20, 95% confidence interval 0.91 to 11.17, $P = .069$) and highest for bovine Melody valves (hazard ratio 11.89, 95% confidence interval 2.91 to 48.48, $P < .001$) compared to homografts. Possible explanations were the preponderance of participants with the Melody valve who had at least two prior conduits implanted, endothelial lesions from the Melody stent, progressive deterioration of the underlying conduit, or the inability to remove degenerated tissue during the procedure. The authors called for

adequately powered, prospective studies to guide management and optimal patient selection and prosthetic choice. 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. We deleted Local Coverage Determinations L33777 and L35094 that had been retired, resulting in deleting the Medicare section of coverage.

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

In 2022, Jones and colleagues performed a long-term follow up study beginning in 2007 and concluded in 2020, of the Melody TPV valve. A 171 participants were enrolled in which 150 (median age of 19) had received the Melody transcatheter pulmonary valve replacement procedure. Of them, 149 participants implanted for greater than 24 hours, were continued to be followed. The primary outcomes at 10 years demonstrated and affirmed the benefits of a Melody TPV via freedom from mortality (90%); reintervention (60%); reoperation (79%) in the participants with a mean right ventricular output tract flow gradient greater or equal to 40 mm Hg. Reduction in Melody valve dysfunction was estimated at 53% and was significantly shorter for children than adults in the study. Freedom from valve implant related endocarditis was 81% (95% CI,69%-89%) with an annualized 2.0% rate of per patient-year (Jones, 2021).

References

On August 18, 2022, 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.