Transcatheter pulmonary valve replacement

Clinical Policy ID: CCP.1264

Recent review date: 11/2025

Next review date: 3/2027

Policy contains: Transcatheter pulmonary valve replacement (TPVR); pulmonary valve insufficiency; pulmonary valve stenosis; right ventricular outflow tract (RVOT); congenital heart disease; Melody; SAPIEN XT; SAPIEN 3; Harmony; Alterra.

Coverage policy

Transcatheter heart valve replacement (e.g., Melody, Harmony, SAPIEN, Alterra systems) is clinically proven and, therefore, may be medically necessary when all criteria are met:

The member must meet criteria for either symptomatic (A) or asymptomatic (B) intervention.

A. Symptomatic Intervention

The member meets all of the following:

- Has symptoms, reduced functional capacity, or arrhythmia attributable to the dysfunction European Society of Cardiology (Baumgartner, 2021); Canadian Cardiovascular Society (Marelli, 2022) ; American College of Cardiology and the American Heart Association (Stout, 2019).
- Has hemodynamic dysfunction meeting the criteria for the corresponding anatomical substrate (either a or b):
  - Dysfunctional Conduit or Bioprosthetic Valve:
    - Pulmonary regurgitation: Moderate or greater (U.S. Food and Drug Administration, 2017).
    - Pulmonary stenosis: Mean right ventricular outflow tract gradient ≥ 35 mmHg (U.S. Food and Drug Administration, 2017).
  - Native or Surgically Repaired right ventricular outflow tract:

- Severe pulmonary regurgitation (defined as severe by echocardiography OR pulmonary regurgitant fraction ≥ 30% by cardiac magnetic resonance imaging) (U.S. Food and Drug Administration, 2021a; U.S. Food and Drug Administration, 2021b).

B. Asymptomatic Intervention

The member meets ALL of the following:

- Has severe hemodynamic dysfunction:
  - Severe pulmonary regurgitation; or
  - Severe pulmonary stenosis (Baumgartner, 2021; Marelli, 2022; Stout, 2019).
- Has one or more of the following objective findings (Baumgartner, 2021; Marelli, 2022):
  - Progressive right ventricular dilation (e.g., RV end-diastolic volume index ≥160 mL/m² OR RV end-systolic volume index ≥80 mL/m²).
  - Progressive right ventricular systolic dysfunction (e.g., <45%).
  - Objective decrease in exercise capacity.
  - Progressive tricuspid regurgitation (at least moderate severity).
  - Sustained atrial or ventricular arrhythmias.
  - (If stenosis is the primary indication): Right ventricular systolic pressure greater than 60 mmHg.

Limitations

- Active bacterial endocarditis or other active infection."
- Unable to tolerate anticoagulation or antiplatelet therapy.
- Transcatheter heart valve replacement is contraindicated and not medically necessary if the member:
- Use of transcatheter valve replacement for mild regurgitation or stenosis without significant hemodynamic compromise.
- Intervention for asymptomatic pulmonary dysfunction without objective findings of physiological compromise (e.g., normal right ventricular volumes and function, normal exercise capacity).
- Has a known intolerance to device materials (e.g., intolerance to cobalt-chromium or Nitinol [titanium or nickel]).

Alternative Covered Services

- Surgical valve repair.
- Surgical valve replacement (e.g., surgical aortic valve replacement, surgical pulmonary valve replacement).

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).

Transcatheter pulmonary valve devices

The Melody Transcatheter Pulmonary Valve (Medtronic, Inc) was the first device approved by the Food and Drug Administration to address right ventricular outflow tract dysfunction via a minimally invasive approach. This device is constructed from a bovine jugular vein valve sewn into a platinum iridium frame (Food and Drug Administration, 2017). It is delivered using the Ensemble Delivery System, which employs a balloon catheter to expand the valve while the heart is beating. Initially approved for right ventricular outflow tract conduits in 2015, its indication was expanded in 2017 to include implantation inside failing bioprosthetic pulmonary valves (U.S. Food and Drug Administration, 2015; 2017). The Melody Transcatheter Pulmonary Valve is indicated for pediatric and adult patients with dysfunctional right ventricular outflow tract conduits or bioprosthetic pulmonary valves presenting with at least moderate regurgitation and/or a mean right ventricular outflow tract gradient of 35 mmHg or greater (Food and Drug Administration, 2017).

To address the needs of patients with native or surgically-repaired right ventricular outflow tracts, which often present different anatomical challenges than conduits, the Food and Drug Administration approved the Harmony Transcatheter Pulmonary Valve System (Medtronic, Inc.) in March 2021. These anatomies are often too large or irregular for traditional balloon-expandable devices. The Harmony Transcatheter Pulmonary Valve utilizes a self-expanding Nitinol (nickel-titanium alloy) frame fitted with a porcine pericardial tissue valve, designed to conform to variable anatomies (Food and Drug Administration, 2021a). It is indicated for pediatric and adult patients with severe pulmonary regurgitation who are clinically indicated for pulmonary valve replacement and received Breakthrough Device status (Food and Drug Administration, 2021a).

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent (Edwards Lifesciences LLC) offers another solution for patients with native or surgically-repaired right ventricular outflow tracts. Approved in December 2021, this system employs a two-stage approach to stabilize the implantation site in challenging anatomies (Food and Drug Administration, 2021b). First, the Alterra Adaptive Prestent, a self-expanding Nitinol frame, is deployed within the right ventricular outflow tract to serve as a docking adaptor. Subsequently, the SAPIEN 3 valve, a balloon-expandable, cobalt-chromium frame with a bovine pericardial tissue valve, is deployed within the present (Food and Drug Administration, 2021b).

The availability of these distinct transcatheter pulmonary valve replacement systems addresses a range of anatomical variations in patients with congenital heart defects. These minimally invasive procedures are associated with reduced risks of bleeding and infection compared to open-heart surgery. These technologies delay the time when a patient requires additional surgery and may reduce the total number of open-heart surgeries a patient requires over their lifetime.

Findings

Clinical guidelines for transcatheter valve replacement have evolved from general recommendations toward position-specific numerical thresholds, particularly for pulmonary interventions where European guidance now expresses a clear procedural preference when anatomy permits. The evidence base for transcatheter pulmonary valve replacement spans multiple device platforms—including the Melody valve, the Harmony self-expanding valve, and the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent—and

draws predominantly from meta-analyses of comparative cohorts alongside pivotal device-specific trials with extended follow-up. Patient selection consistently favors transcatheter therapy in populations at higher surgical risk, complicating direct interpretation of comparative outcomes. A notable exception to the favorable procedural profile emerges in midterm infective endocarditis incidence, where pooled analyses identify both an overall elevation in risk and device-specific variation.

Guidelines

The American College of Cardiology and the American Heart Association (Stout, 2019) base the decision to replace a right ventricle to pulmonary artery conduit on clinical findings rather than fixed size criteria. They recommend valve replacement in adults who report reduced exercise tolerance or arrhythmia when imaging shows at least moderate pulmonary regurgitation or stenosis, and in asymptomatic adults only when severe regurgitation or stenosis has already produced right ventricular dysfunction or dilation. The European Society of Cardiology (Baumgartner, 2021) advances the guidance by setting numerical thresholds and expressing a clear preference for transcatheter pulmonary valve implantation when the anatomy allows. Intervention is advised for symptomatic patients with right ventricular systolic pressure greater than 60 mm Hg or magnetic resonance regurgitant fraction greater than 30 to 40 percent, and for asymptomatic patients when any of the following occur: indexed end-systolic volume at least 80 mL/m², indexed end-diastolic volume at least 160 mL/m², right ventricular systolic pressure greater than 80 mm Hg, measurable exercise decline, tricuspid regurgitation of at least moderate grade, or progressive right ventricular systolic dysfunction.

The society also lists contraindications such as occluded systemic veins, active infection, unsuitable outflow tract anatomy, or close coronary proximity, and advises surgery when additional procedures are required. The Canadian Cardiovascular Society (Marelli, 2022) mirrors the same right ventricular volume cutoffs but lowers the magnetic resonance regurgitant fraction that defines significant pulmonary regurgitation to 25 percent. It supports either surgical or transcatheter replacement for symptomatic patients who meet this threshold, and for asymptomatic patients who meet the volume limits, show right ventricular dysfunction, develop obstruction in the outflow tract, or exhibit objective loss of exercise capacity.

Evidence reviews

Across comparative syntheses, transcatheter pulmonary valve replacement matched or improved survival relative to surgery, with no early mortality difference but lower mortality at longest follow-up. Eleven studies (n=4,364) showed lower in-hospital mortality and lower longest follow-up mortality with transcatheter pulmonary valve replacement, while 30-day mortality did not differ (Zhou, 2019). A meta-analysis of 28 studies (n=16,150) found 36 percent lower all-cause mortality during follow-up with transcatheter pulmonary valve replacement versus surgery (odds ratio 0.64, 95 percent confidence interval 0.43 to 0.95), with no 30-day difference (Chongmelaxme, 2025). Procedural morbidity and convalescence favored the transcatheter approach, with fewer procedure-related complications and a mean hospital stay shorter by about four days than surgery (Ribeiro, 2020; Zhou, 2019).

Hemodynamics were at least noninferior and often better with transcatheter implantation. Meta-analyses reported less significant pulmonary regurgitation during follow-up and a trend toward lower transpulmonary gradients after transcatheter pulmonary valve replacement (Ribeiro, 2020; Zhou, 2019). Device-specific series aligned. After Melody implantation into conduits or surgical bioprostheses, the discharge mean Doppler gradient was 17 mm Hg and at 10 years 72 percent of patients had trace or no pulmonary regurgitation (Jones, 2022). In dilated native right ventricular outflow tracts treated with the Edwards SAPIEN 3 system with the Alterra Adaptive Prestent, device success was 100 percent in 15 patients, the median post-procedural peak-to-peak gradient was 6 mm Hg, and no moderate or severe pulmonary regurgitation occurred through 6 months (Shahanavaz, 2020). Harmony valve midterm follow-up showed mild-or-less pulmonary regurgitation in all TPV22 and 96 percent of

TPV25 recipients at 3 years, with magnetic resonance imaging documenting sustained right ventricular reverse remodeling to 2 years (Morray, 2025).

Infective endocarditis occurred more often after transcatheter pulmonary valve replacement than after surgery in pooled comparative data, with risk modulated by substrate and residual gradients. Meta-analyses estimated about three-fold higher odds of infective endocarditis with transcatheter pulmonary valve replacement versus surgery (Ribeiro, 2020; Chongmelaxme, 2025). A multicenter registry of 2,476 transcatheter recipients reported an annualized incidence of 2.2 per 100 patient-years, with younger age, prior endocarditis, and higher immediate post-implant gradient as independent predictors; valve type was not an independent predictor after adjustment (McElhinney, 2021). Device-focused syntheses nevertheless showed lower pooled endocarditis incidence after Sapien balloon-expandable valves than after Melody—about an 80 percent relative reduction (Machanahalli Balakrishna, 2023). Contemporary single-center cohorts with mixed anatomies confirmed that residual obstruction and smaller effective diameters were associated with both infective endocarditis and secondary pulmonary valve replacement, while endocarditis after Sapien valves was uncommon (Houeijeh, 2023). Narrative synthesis of position-specific comparisons reached similar conclusions (Slouha, 2023).

Durability and reintervention were broadly comparable overall, with device- and anatomy-specific gradients. Meta-analyses showed no significant difference in reintervention during follow-up between transcatheter and surgical pulmonary valve replacement (Ribeiro, 2020; Chongmelaxme, 2025). Long-term Melody outcomes reported 10-year freedom from any reintervention of 60 percent and from reoperation of 79 percent; reintervention risk was lower in prestented or otherwise protected conduits and higher with greater residual gradients and younger age (Jones, 2022). In native outflow tracts, Harmony midterm data showed infrequent reintervention for obstruction or thrombosis treated with valve-in-valve and one surgical explant for stent fracture; freedom from reintervention at 3 years was about 90 percent (Morray, 2025). Early feasibility with Alterra-assisted SAPIEN 3 showed no valve dysfunction to 6 months and 1-day median discharge in anatomies previously unsuitable for balloon-expandable valves (Shahanavaz, 2020). Baseline anatomy differed across comparators in pooled cohorts—transcatheter recipients were less likely to have a native or patched outflow tract and more often treated for isolated stenosis—underscoring conduit or valve-in-valve contexts for balloon-expandable devices versus native outflow tract indications for self-expanding or Alterra-assisted systems (Ribeiro, 2020; Jones, 2022).

In 2025, we transitioned CCP.1264 from a Melody-only policy to a device-agnostic transcatheter pulmonary valve replacement policy covering Melody, Harmony, and Edwards Sapien 3 with the Alterra Adaptive Prestent, and extended eligibility to native or surgically repaired right ventricular outflow tracts. We restructured coverage into symptomatic and asymptomatic pathways with explicit numerical thresholds and added contraindications, including intolerance to device materials. We expanded citations to include regulatory approvals and summaries and new evidence syntheses and cohorts, including systematic reviews and meta-analyses (Zhou 2019; Ribeiro 2020; Chongmelaxme 2025), a multicenter registry on infective endocarditis (McElhinney 2021), and device-focused series on durability and hemodynamics (Jones 2022; Shahanavaz 2020; Morray 2025).

References

On October 21, 2025, 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.

11/2024: Policy references updated.

11/2025: Policy references updated. Policy transitioned to be device agnostic, and coverage criteria revised.