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Transcatheter Pulmonary Valve Implantation

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Coverage

Transcatheter pulmonary valve implantation with a U.S. Food and Drug Administration approved valve **may be considered medically necessary** for individuals with congenital heart disease and current right ventricular outflow tract (RVOT) obstruction or regurgitation including the following indications:

- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Individuals with native or patched RVOT with at least moderate pulmonic regurgitation;
- Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
- Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

Transcatheter pulmonary valve implantation **is considered experimental, investigational and/or unproven** for all other indications.

Policy Guidelines

None.

Description

Transcatheter pulmonary valve implantation (TPVI) is a less invasive alternative to open surgical pulmonary valve replacement or reconstruction for right ventricular outflow tract (RVOT) obstruction. Percutaneous pulmonary valve replacement may be indicated for congenital pulmonary stenosis. Pulmonary stenosis or regurgitation in a patient with congenital heart disease who has previously undergone RVOT surgery are additional indications. Patients with prior congenital heart disease repair are at risk of needing repeated reconstruction procedures.

Congenital Heart Disease

Congenital heart disease, including tetralogy of Fallot, pulmonary atresia, and transposition of the great arteries, is generally treated by surgical repair at an early age. This involves reconstruction of the RVOT and pulmonary valve using a surgical homograft or a bovine-derived valve conduit. These repairs are prone to development of pulmonary stenosis or regurgitation over long periods of follow-up. Individuals living with congenital heart disease also face disparities in social determinants of health and the inability to obtain quality lifelong care for their condition which can contribute to inequities in morbidity and mortality. (1)

Because individuals with surgically corrected congenital heart disease repair are living into adulthood, RVOT dysfunction following initial repair has become more common. Calcification of the RVOT conduit can lead to pulmonary stenosis, while aneurysmal dilatation can result in pulmonary regurgitation. RVOT dysfunction can lead to decreased exercise tolerance, potentially fatal arrhythmias, and/or irreversible right ventricular dysfunction. (2)

Treatment

Treatment options for pulmonary stenosis are open surgery with valve replacement, balloon dilatation, or percutaneous stenting. (2) The established interventions for pulmonary regurgitation are primarily surgical, either reconstruction of the RVOT conduit or replacement of the pulmonary valve. The optimal timing of these interventions is not well understood. (3)

Regulatory Status

Devices for transcatheter pulmonary valve implantation were initially cleared from marketing by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process or used off-label until approved by the FDA through the premarket approval (PMA) (see Table 1).

Table 1. Regulatory Status of Transcatheter Pulmonary Valve Implantation Devices

Device	Manufacturer	Date Approved	PMA Number	Indications

Melody® Transcatheter Pulmonary Valve (TPV)	Medtronic	Jan 2010	H080002 (HDE)	Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit
Melody® TPV	Medtronic	Jan 2015	P140017	Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit
Melody® TPV	Medtronic	Feb 2017	P140017/S005	Valve-in-valve for patients with a dysfunctional surgical bioprosthetic pulmonary valve
SAPIEN XT™ Transcatheter Heart Valve (pulmonic)	Edwards Lifesciences	Feb 2016	P130009/S037	Pulmonary valve replacement for pediatric and adult patients with a dysfunctional, noncompliant RVOT conduit
Harmony™ TPV	Medtronic	Mar 2021	P200046	Pulmonary valve for pediatric and adult patients with severe pulmonary regurgitation

HDE: humanitarian device exemption; PMA: premarket approval; RVOT: right ventricular outflow tract

In January 2010, the Melody® TPV and the Ensemble® Transcatheter Valve Delivery System (Medtronic) were approved by the FDA under the HDE program for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that is 16 mm or greater in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
  - Regurgitation: moderate-to-severe regurgitation, or
  - Stenosis: mean RVOT gradient ≥35 mm Hg.

On January 27, 2015, approval of the Melody system was amended to a PMA because the FDA determined that the device represented a breakthrough technology. The PMA was based, in part, on 2 prospective clinical studies, the Melody TPV Long-term Follow-up Post Approval Study and the Melody TPV New Enrollment Post Approval Study.

On February 24, 2017, approval of the Melody system was expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve).

The Edwards SAPIEN XT™ Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) was approved by FDA in 2016 "for use in pediatric and adult patients with a dysfunctional, noncompliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and:

- Pulmonary regurgitation ≥ moderate and/or
- Mean RVOT gradient ≥ 35 mmHg."

The approval for the pulmonic valve indication is a supplement to the 2014 PMA for use of the Edwards SAPIEN XT Transcatheter Heart Valve System for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis and who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., Society of Thoracic Surgeons operative risk score ≥8% or at a ≥15% risk of mortality at 30 days).

The Harmony™ Transcatheter Pulmonary Valve (Medtronic) received breakthrough technology status in 2019 and PMA in 2021. This device is indicated "for use in pediatric and adult patients with severe pulmonary regurgitation (determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement."

FDA product code: NPV

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less

common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

TRANSCATHETER PULMONARY VALVE IMPLANTATION

Clinical Context and Therapy Purpose

The purpose of transcatheter pulmonary valve implantation (TPVI) is to provide a treatment option that is an alternative to or an improvement on surgical pulmonary valve implantation (SPVI) for individuals with congenital heart disease.

Interventions for right ventricular outflow tract (RVOT) dysfunction in patients with congenital heart disease often require numerous repeat open heart procedures for patients who live into adulthood. Transcatheter pulmonary valve replacement offers a less invasive treatment option for patients with congenital heart disease and RVOT dysfunction. It is possible that a less invasive valve replacement technique could spare patients from multiple repeat open heart procedures over long periods of follow-up.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with congenital heart disease and RVOT or regurgitation, including the following clinical situations:

- Right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Native or patched RVOT with at least moderate pulmonic regurgitation;
- Right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
- Native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

Interventions

The therapy being considered is TPVI. U.S. Food and Drug Administration (FDA)-Approved Devices are described below.

The Melody Transcatheter Pulmonary Valve (TPV) and the Ensemble Transcatheter Valve Delivery System are used together for percutaneous replacement of a dysfunctional pulmonary valve. The Melody valve consists of a section of bovine jugular vein with an intact native venous valve. The valve and surrounding tissue are sutured within a platinum-iridium stent scaffolding. The transcatheter delivery system consists of a balloon-in-balloon catheter with a retractable sheath and distal cup into which the valve is placed. The procedure is performed on a beating heart without the use of cardiopulmonary bypass. The Melody valve is first crimped to fit into the delivery system. It is introduced through the femoral vein and advanced into the right side of the heart and put into place at the site of the pulmonary valve. The inner balloon is inflated to open the artificial valve, and then the outer balloon is inflated to position the valve into place.

The FDA, under the humanitarian device exemption (HDE) program, cleared these devices for marketing for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

- Existence of a full (circumferential) RVOT conduit that is 16 mm or greater in diameter when originally implanted, and
- Dysfunctional RVOT conduits with clinical indication for intervention, and either:
  - regurgitation: moderate-to-severe regurgitation, or
  - stenosis: mean RVOT gradient ≥35 mm Hg.

In 2017, approval of the Melody system was expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve).

The Edwards SAPIEN XT Transcatheter Heart Valve (Pulmonic) (Edwards Lifesciences) is composed of a stainless steel frame with bovine pericardial tissue leaflets and available in 23- and 26-mm sizes. It includes a delivery accessories system. It is indicated "for use in pediatric and adult patients with a dysfunctional, noncompliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and:

- Pulmonary regurgitation ≥ moderate and/or
- Mean RVOT gradient ≥ 35 mm Hg."

The Harmony TPV is composed of self-expanding Nitinol wire struts, a knitted polyester fabric graft, and a porcine pericardial tissue valve. It includes a delivery accessories system, and is indicated for "use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction $\underline{\geq}$ 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement."

Comparators

The following practice is currently being used to treat this indication: open surgical pulmonary valve implantation or reconstruction.

Outcomes

The outcomes of interest are

- Overall survival;
- Symptoms: a surrogate for recurrence of symptoms would be needed for reintervention;
- Functional outcomes: functional improvement in New York Heart Association (NYHA) functional class;
- Quality of life;
- Hospitalizations: length of stay after the procedure;
- Treatment-related mortality: periprocedural mortality;
- Treatment-related morbidity: periprocedural complications and infective endocarditis.

Follow-up at short-term (perioperative), mid-term (3-7 years), and long-term (>7 years) are of interest to monitor outcomes and reintervention rates.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Food and Drug Administration-Approved Devices and Indications

Systematic Reviews

Systematic Review of Transcatheter Versus Surgical Pulmonary Vein Replacement

Systematic review characteristics and results are described in Tables 2 and 3.

Ribeiro et al. (2020) performed a systematic review and meta-analysis of 18 nonrandomized comparative studies of surgical pulmonary valve replacement (SPVR) and transcutaneous pulmonary valve replacement (TPVR). (4) No RCTs were identified. There were no significant differences in age or gender between the groups, but there were significant differences in anatomic and functional characteristics. Patients undergoing TPVR were more likely to have pulmonary stenosis (29% vs. 12%), while those undergoing SPVR were more likely to have pulmonary regurgitation (57% vs. 22%). There were large numerical differences in the presence of a native ventricle outflow tract/transannular patch (TPVR: 16%, SPVR: 60%; odds ratio [OR]: 0.20; 95% confidence interval [CI]: 0.03 to 1.31), but this difference did not achieve statistical significance. Meta-analysis suggested a reduction in peri-procedural complications (16.5% vs. 41.3%, p=.01) and length of hospital stay (-4.32 days) with the percutaneous approach, with an increased risk of infective endocarditis (5.8% vs. 2.7%, p<.001). There were no significant differences in early mortality, late mortality, and need for reintervention. Interpretation is limited by the differences in baseline characteristics between the 2 groups and the possibility of selection bias. The authors noted that a number of patients underwent SPVR because they were not candidates for TPVR due to RVOT anatomy and/or other cardiac defects.

Table 2. Systematic Review Characteristics

Study	Dates	Trials	Participants	Studies (range)	Design	Duration
Ribeiro et al. (2020) (4)	To 2019	29	Patients undergoing TPVR or SPVR	18 (6-11)	Non-randomized comparative studies of any design	

SPVR: surgical pulmonary valve replacement; TPVR: transcatheter pulmonary valve replacement.

Table 3. Systematic Review Results

Study	Early Mortality	Periprocedural Complications	Length of Hospital Stay	Mid-term Mortality	Infective Endocarditis	Need for Reintervention
Studies	11	7	10	6	10	9
Total N	6071	2284	5174	1503	2338	4692
TPVR	0.2%	16.5%		1.5%	5.8%	2.5%
SPVR	1.2%	41.3%		2.7%	2.7%	5.3%
Diff or OR (95% CI)	0.56 (0.19 to 1.59)	0.38 (0.18 to 0.82)	-4.32 days (-5.33 to -3.31)	0.78 (0.30 to 2.00)	3.09 (1.89 to 5.06)	0.51 (0.17 to 1.55)
p	.27	.01	<.001	.60	<.001	.24
I^2	0%	73%	100%	0%	0%	71%

CI: confidence interval; Diff: difference; OR: odds ratio; SPVR: surgical pulmonary valve replacement; TPVR: transcatheter pulmonary valve replacement.

Nonrandomized Studies

Melody Transcatheter Pulmonary Valve - Pivotal and Post-Approval Studies

The multicenter U.S. Melody TPV trial was a prospective uncontrolled trial designed to assess the safety, procedural success, and short-term effectiveness of the Melody TPV. The Summary of Safety and Probable Benefit to support the approval of a HDE to market the Melody TPV was based on clinical data from 99 subjects who were catheterized for potential implantation with the TPV from January 2007 through December 2008, with expected follow-up and adverse event data on these subjects current through March 2009. (5) Approved indications included RVOT dysfunction, defined as pulmonic regurgitation (moderate or greater) or pulmonic stenosis (mean gradient, ≥35 mm Hg). Also, a circumferential RVOT conduit should exist that is 16 mm or greater in diameter when originally implanted.

The investigators planned to follow 150 patients over 5 years. Eligibility criteria included a dysfunctional RVOT conduit or a dysfunctional bioprosthetic pulmonary valve, plus evidence of heart failure. For patients with NYHA class I heart failure, a Doppler mean gradient of 40 mm Hg or greater or severe pulmonary regurgitation was required; for patients with NYHA class II to IV heart failure, a mean gradient of 35 mm Hg or greater or moderate pulmonary regurgitation was required. These inclusion criteria generally are indications for pulmonary valve replacement. The primary outcomes were defined as procedural success, adverse events from the procedure, and effectiveness, as measured by the proportion of patients with acceptable valve function at 6 months.

Trial results have been published in several reports. (3, 6, 7) Short- and medium-term outcomes for 136 patients who underwent attempted TPVI were reported by McElhinney et al. (2010). (3) A total of 124 (91.2%) of 136 patients had successful implantation. In 12 patients, implantation was not possible due to anatomic or other intraprocedural findings. One (0.7%)

death occurred as a result of the procedure, and serious adverse events occurred in 8 (6%) of 136 patients. Adverse events included coronary artery dissection, conduit rupture/tear, wide complex tachycardia, respiratory failure, femoral vein thrombosis, and perforation of the pulmonary artery.

Ninety-four patients with successful implantation had reached the 6-month follow-up at the time of publication. Acceptable valve function, defined as mild pulmonary regurgitation or less on echocardiography, was present in more than 90% of patients. Right ventricular (RV) pressure and RVOT gradient improved following the procedure, and 71 (75.5%) of 94 were in NYHA class I heart failure at 6 months. During follow-up, stent fractures were diagnosed in 25 (20.2%) of 124 patients, and 9 (7.3%) of 124 required implantation of a second valve.

Cheatham et al. (2015) reported on outcomes up to 7 years following TPVI for the 148 patients who received and were discharged with a TPV in the US Melody TPV trial (of 171 patients enrolled). (7) Of the 171 patients enrolled, 167 underwent catheterization, 150 had a Melody valve implanted, and 148 of those survived to discharge with the Melody valve in place. On echocardiogram at discharge, pulmonary regurgitation was absent/trivial or mild in 140 patients and 5 patients, respectively, which represented a significant improvement from baseline. Over a median follow-up of 4.5 years (range, 0.4 to 7.0 years), 4 deaths occurred. During the follow-up period, 32 patients required a reintervention on RVOT, 25 of which were TPV reinterventions. A total of 11 patients required Melody valve explantation. Among the 113 patients who were alive and free from reintervention at a median of 4.5 years post-implantation, the most recent RVOT gradient was unchanged from early after valve implantation. Functional outcomes generally improved during the study: before TPVI, 14% of patients were in NYHA class I and 17% were in class III or IV. At every post-implantation annual evaluation, at least 74% of patients were in class I and no more than 1% to 2% were in class III or IV.

A secondary publication (2012) from the US Melody TPV trial focused on the change in exercise function following TPVI. (8) Patients completed a standardized cardiopulmonary regimen 2 months before and 6 months after TPVI. Results of pre- and postexercise parameters were available for 94 to 114 patients, depending on the specific outcome. Numerous physiologic outcome measures were reported, with some showing a statistically significant change between the 2 time points, and others not. For example, there was a significant increase in the percent predicted maximal workload from 65.0% at baseline to 68.3% at follow-up ($p<.001$) and a significant decrease in the ratio of minute ventilation to CO_2 production from 30.8 at baseline to 29.1 at follow-up ($p<.001$). In contrast, there were no significant changes in peak oxygen consumption or spirometric measures of pulmonary function. This trial reported modest benefits in exercise parameters for patients treated with TPVI. The results were limited by the lack of a control group and by a large number of patients who did not have completed exercise results available (approximately one-third of total).

The 2015 premarket approval (PMA) of the Melody TPV was based on the interim analysis and a retrospective pooling analysis of the 2 post approval studies conditioned by the prior

humanitarian device exemption. An additional supplemental dataset from the Melody TPV European and Canadian Post-Market Surveillance Study (PMSS) was included in the PMA. (9)

Armstrong et al. (2014) published 1-year follow-up results of the Melody TPV Long-term Follow-up Post Approval Study (PAS); a prospective study designed to evaluate the short-term hemodynamic changes following device implantation. (10) The study used historical controls from the Melody pivotal investigational device exemption (IDE) trial described above to investigate whether the short-term effectiveness of the device was noninferior to results shown in the IDE trial. PAS enrolled 120 subjects, 101 of whom underwent attempted TPVI. Patient selection was based on the criteria used in the IDE trial but did not include the age (≥5 years of age) and weight (≥30 kg) limitations. Procedure-related significant adverse events occurred in 16 patients (13.3% of total cohort; 15.8% of those who had an attempted TPVI), the most common of which was a confined conduit tear. Procedural success occurred in 99 subjects (98% of those with an attempted TPVI). At 1-year follow-up, the proportion of patients in NYHA class I heart failure increased from 35% at baseline to 89%. Of the 99 patients implanted for at least 24 hours, 87 had acceptable TPV hemodynamic function confirmed at 6 months (96.7% of those with evaluable echocardiographic data, 87.9% of entire cohort) and 82 had acceptable TPV hemodynamic function at 1 year (94.3% of those with evaluable echocardiographic data, 82.8% of the entire cohort). Following the procedural period, serious device-related adverse events occurred in 8%, most commonly endocarditis (n=3 patients).

Gillespie et al. (2015) evaluated results of TPVI after a Ross procedure in a retrospective review of pooled findings from the US Melody TPV trial and PAS and an additional European registry, the manufacturer-sponsored Melody TPV PMSS conducted in Canada and Europe (NCT00688571). (11) In the pooled sample (N=358 patients), 67 (19%) had a prior Ross procedure. A Melody valve was successfully implanted in 56 (84%) of 67 Ross patients who underwent catheterization with intent for TPVI. Six (9%) patients had symptomatic coronary artery compression after TPVI or did not undergo implantation due to the risk of compression. RV hemodynamics generally improved after TPVI, but RVOT reinterventions were required in 12 of 55 patients discharged from the implant hospitalization with the Melody valve in place.

The Melody TPV New Enrollment Study was intended to roll in the new patient enrollment study specified as a condition of approval for the Melody TPV HDE on January 25, 2010. (12) This study used the protocol dated September 24, 2013, Version 2, included in H080002/S015. The study is a prospective, nonrandomized, multicenter, historically controlled clinical trial, designed to assess the post market performance of the Melody TPV in a representative population of providers and patients, with 5-year follow-up. The primary endpoint is freedom from TPV dysfunction, with a performance goal of 75% or greater at 6 months. Secondary end points include procedural success, serious procedural- and device-related adverse events, stent fracture, reintervention on the TPV, surgical replacement of the RVOT conduit, death (all-cause, procedure-related, and device-related), and NYHA classification.

The February 2017 approval of the Melody system expanded to include patients with a dysfunctional surgical bioprosthetic valve (valve-in-valve) is based on data pooled from 3 sources (13):

- Melody TPV Long-term Follow-up PAS: 8 patients;
- Melody TPV New Enrollment PAS: 17 patients;
- Real-World Data: 100 patients.

Of 125 patients pooled from the 3 studies listed above, 56.8% (71) patients were available for analysis at study completion, the 1-year postimplant visit. Baseline pooled subject median age was 22.0 years (range, 5.0-79 years), with 45.6% female and 54.4% male. Tetralogy of Fallot was the most common congenital heart disease diagnosis recorded in 72.8% of subjects, 66.4% of whom had pulmonary stenosis or atresia. There was no mortality for any cause, major stent fracture, occurrence of endocarditis, RVOT reoperation, or catheter reintervention among available patients at 1 year. Procedural failure as defined by more than trivial pulmonary regurgitation by angiography postimplant occurred in 10.1% (12/119) subjects. There were no device explants within 24 hours of implantation. The mean RVOT gradient was reduced from 29.5 mm Hg at baseline to 14.3 mm Hg at 1-year post implantation. In this PMA, existing clinical data were not leveraged to support approval of a pediatric patient population. This submission included pediatric data to support the pediatric indication, and no extrapolation was necessary.

Jones et al. (2021) reported on 10-year outcomes of the Melody IDE trial. (14) There were 171 patients enrolled in the Melody IDE trial, and 58 of those patients completed the 10-year follow-up assessment. The primary outcome assessed was freedom from TPV dysfunction; additional outcomes were time-dependent (i.e., time to catheter reintervention, surgical RVOT reoperation, stent fracture, and death). The estimated freedom at 10 years from TPV dysfunction was 53% (95% CI, 40% to 65%) and was significantly shorter in children than in adults. The estimated freedom from mortality at 10 years was 90% (95% CI, 79% to 96%) and did not differ significantly between age groups. The estimated freedom from any TPV reintervention and freedom from RVOT reoperation were 60% (95% CI, 47% to 71%) and 79% (95% CI, 67% to 87%), respectively.

<u>Comparative Observational Studies</u>

Georgieve et al. (2020) interrogated a database of all patients who had undergone TPVI (n=241) with the Melody valve or SPVR (n=211) between 2006 and 2018 at a European heart center. (15) If technically possible, TPVI was preferred. Patients with inappropriate anatomy of the coronary arteries or with large RVOTs were treated with SPVR. The median follow-up time was 5.4 years (3 months to 12.5 years). Estimated survival after 10 years was 94% in the Melody group and 92% in the SPVR group. Infective endocarditis tended to be higher with the percutaneous approach, but there was no difference in survival of the implanted pulmonary valve (TPVI: 80% vs. SPVR: 73%, p=.46). There were a number of significant differences in patient characteristics and follow-up, limiting interpretation of these results.

Edwards Sapien XT Transcatheter Heart Valve (Pulmonic) - Pivotal Study

Edwards Lifesciences, manufacturer of the SAPIEN transcatheter heart valve (THV), performed a clinical study to establish the safety and efficacy of its pulmonic implantation in patients with dysfunctional RVOT conduits in the United States under IDE G060242 (COMPASSION trial). Data from this clinical study were the basis for the PMA decision for the pulmonary valve implantation indication. Patients were treated between April 2008 and November 2014. The database supplement reflects data collected through March 2015 and includes 81 patients. There were 7 investigational sites. (31)

This prospective, nonrandomized, multicenter clinical study assessed the safety and effectiveness of pulmonic implantation of the SAPIEN THV in patients with dysfunctional RVOT conduits requiring treatment for moderate or severe pulmonary regurgitation by transthoracic echocardiogram (TTE) and/or RVOT conduit obstruction with a mean gradient of 35 mm Hg or higher by TTE. The SAPIEN THV, the first-generation valve of the SAPIEN device line, is no longer available for distribution. The valve sizes used in the COMPASSION trial included the 23- and 26-mm sizes, which were the only sizes available for the SAPIEN THV. The 29-mm valve size was not evaluated in the COMPASSION trial. Most data derived from patients who received the 23-mm THV size. Aortic experience with the 29-mm SAPIEN XT THV showed no significant difference in the long-term performance compared with the 23- and 26-mm sizes. Furthermore, no observed results suggested that the 29-mm valve size would perform worse than other available sizes in the pulmonic location.

All patients were scheduled to return for follow-ups at day 1 postprocedure, discharge, 30 days, 6 months, 12 months, and annually after that for 5 years postoperatively. Baseline evaluation included TTE, x-ray, magnetic resonance imaging, or computed tomography, angiogram, and electroencephalograph. Assessment of NYHA class, magnetic resonance imaging or computed tomography, and angiogram were part of the 6-month evaluation.

The primary end point was freedom from the device- or procedure-related death and/or reintervention at 1 year. The secondary end points were:

- Freedom from major adverse cardiac and cerebrovascular events at 6 months. Major adverse cardiac and cerebrovascular events were defined as all-cause mortality, myocardial infarction, reintervention, vascular injury resulting in the need for an unplanned vascular intervention, stroke, and pulmonary embolism.
- Functional improvement at 6 months as defined by:
    - Improved valve hemodynamics as demonstrated via TTE:
        - Decrease in pulmonary regurgitation to mild or less for regurgitant lesions;
        - Decrease in the mean pulmonary gradient to less than 30 mm Hg for stenotic lesions;
        - Improvement in both pulmonary regurgitation and gradient (above) for mixed lesions.
    - Improvement of 1 or more NYHA functional classes from baseline for patients in NYHA functional classes $\geq$2 at baseline.
    - Freedom from recurrent pulmonary stenosis.

Of 81 patients enrolled in the PMA study, 2 patients were screening failures, 9 patients did not receive the valve, another received the valve in a nontarget location. Therefore, 69 patients were available for analysis in the valve implant population at study completion.

The median duration of follow-up for the safety population was 3.04 years (range, 0 to 5.31 years). Males were 65.8% of the population, and 63.3% were at least 22 years of age. The primary indications for valve implantation were pulmonary stenosis (8.9%), pulmonary regurgitation (12.7%), and both stenosis and regurgitation (78.5%). The primary etiology requiring reconstruction of the RVOT and placement of a pulmonary conduit for the safety population was tetralogy of Fallot (42%).

The prespecified performance goal for the primary end point was 75%. The primary outcome was met by 100% of patients; there were 3 reintervention events. At 5 years, the primary outcome using a Kaplan-Meier estimate was 77.1%. Because there were no device- or procedure-related patient deaths at 5 years, the incidence of reinterventions solely contributed to the estimate.

Freedom from reintervention to 5 years for the valve implant population using a Kaplan-Meier estimate was reported by type of reintervention: (a) freedom from surgical pulmonic valve repair was 98.3% at 1 year and 91.8% at 5 years; (b) freedom from TPVI was 97.1% at 1 year and 85.8% at 5 years; (c) freedom from balloon valvuloplasty was 100% at 1 year and 93.7% at 5 years; and (d) freedom from other types of reintervention was 100% at 1 year and 97.9% at 5 years.

For secondary outcomes, freedom from major adverse cardiac and cerebrovascular events at 6 months in the valve implant population was 94.1%. Because 2 (2.5%) of 79 patients experienced a device migration early in the trial, the instructions for use were modified. No other device migrations subsequently occurred in the trial. Serious adverse events for RVOT conduit ruptures occurred in 5 (6.3%) of 79 patients. These 5 ruptures were related to balloon valvuloplasty or placement of a prestent; no ruptures occurred during placement of the SAPIEN THV. There was 1 neurologic event (not stroke), 1 thromboembolism, and 4 endocarditis events at the 1-year follow-up.

Adjunctive analyses of safety and effectiveness stratified by patients ages 21 years or younger at baseline versus patients ages 22 years or older at baseline were conducted. The COMPASSION study was not designed to investigate the differences in outcomes between age groups and, therefore, no statistical inferences can be made.

The analysis of functional improvement outcomes by age group is summarized in Table 4.

Table 4. Edwards Sapien XT Transcatheter Heart Valve (Pulmonic) PMA Approval Study: Overall Functional Improvement by Age Group for Valve Implanted Population

End Points	Age 21 or Younger (n=27)	Age 22 or Older (n=42)

	Outcome Rate, n/N (%)		Outcome Rate, n/N (%)	
	1 Year	**5 Year**	**1 Year**	**5 Year**
Overall functional improvement	18/22 (85.7)	3/7 (42.9)	29/33 (87.9)	5/8 (62.5)
Improved valve function	19/19 (100.0)	5/5 (100.0)	28/30 (93.3)	6/6 (100.0)
Functional improvement in NYHA class	13/14 (92.9)	4/4 (100.0)	32/33 (97.0)	8/8 (100.0)
Freedom from recurrent pulmonary stenosis	18/19 (94.7)	5/9 (55.6)	31/31 (100.0)	7/10 (70.0)
Improved gradient	7/8 (87.5)	3/3 (100.0)	7/8 (87.5)	2/2 (100.0)

NYHA: New York Heart Association; PMA: premarket approval.

Overall functional improvement was defined by the following 4 categories: (a) improved valve function demonstrated by a decrease in pulmonary regurgitation to mild or less per TTE at visit for patients with moderate or more (>2) pulmonary regurgitation at baseline, (b) functional improvement from baseline of 1 or more NYHA functional classes at visit for patients with baseline NYHA functional class of 2 or higher, (c) freedom from recurrent pulmonary stenosis at visit, and (d) improved valve function demonstrated by a decrease in pulmonary stenosis mean gradient to less than 30 mm Hg for patients with pulmonary stenosis mean gradient greater than 30 mm Hg at baseline. Patients with mild or less (≤2+) pulmonary regurgitation at baseline only use categories b, c, and d to determine overall functional improvement. Patients with a NYHA functional class of less than 2 at baseline only use categories a, c, and d to determine overall functional improvement. Patients treated for indications other than pulmonary stenosis only use categories a, b, and d for overall functional improvement. Patients with pulmonary stenosis mean gradient less than 30 mm Hg at baseline only use categories a, b, and c for overall functional improvement.

Harmony Transcatheter Pulmonary Valve - Pivotal and Post-Approval Studies
A summary of the U.S. FDA Summary of Safety and Effectiveness (2021) (16) for the Harmony TPV is shown in Tables 5 and 6.

There were 70 patients in the implanted cohort. Twenty were from the feasibility phase (NCT01762124), 31 were in the pivotal phase (NCT02979587) with the current TPV 22 and TPV 25 devices, and 19 were in the pivotal cohort with an earlier version (cTPV 25). Technical success was achieved in 95.7% of implantations, and the clinical endpoint of acceptable hemodynamic function without reintervention at 6 months was met in 89.2% of patients. The proportion of patients with severe pulmonary regurgitation decreased from 84.4% at baseline to 1.7% at 6 months. Four out of 70 patients (5.7%) required explant of the TPV; 2 were in the feasibility phase and 2 were with a prior version of the device. There were no explants with the current devices in the pivotal study and no mortalities up to the 6-month follow-up. Quality of life, measured by the 36-item short form survey, was improved most in the areas of physical functioning and role limitations due to physical health.

Five-year outcomes from the early feasibility study were published in 2021 in the form of a research letter, demonstrating sustained valve function and freedom from moderate-to-severe valve or perivalvular leak. (17) There were no additional explanations beyond the 2 previously reported and no reports of endocarditis. One sudden cardiac death of unknown relatedness to the device occurred 3.5 years post-implantation.

In 2023, Gillespie et al. reported 1-year safety and efficacy outcomes from a pooled cohort of participants from the Early Feasibility Study (NCT01762124), the Pivotal Study (NCT02979587), and the Continued Access Study (under the same protocol as the Pivotal Study). (18) Overall, 87 individuals within the 3 combined studies received Harmony valves. There were no procedure- or device-related mortality events at 30 days, and no deaths of any cause through 1 year. At 1 year, 98% of individuals who received the current commercially available device and 91% of those who received an earlier version of the device were free from the composite outcome of pulmonary regurgitation, stenosis, and reintervention. Follow-up to 10 years is planned to assess long term valve performance and durability.

Table 5. Summary of Pivotal Study Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
U.S. FDA SSED (2021) (16)	United States	70 patients with severe pulmonary regurgitation and a clinical indication for surgical placement of a pulmonary artery conduit or prosthetic valve	Harmony TPV	5 years

U.S. FDA SSED: United States Food and Drug Administration Summary of Safety and Effectiveness; TPV: Transcatheter pulmonary valve.

Table 6. Summary of Pivotal Study Results

Study	Acceptable Hemodynamic Function at 6 months[a]	Technical Success	Freedom from Device Failure at 6 months	Mortality at 6 months	Explant of the TPV
U.S. FDA SSED (2021) (16)					
N	68	70	70	70	71
	58 (89.2%)	67 (95.7%)	84.3%	0%	5.7%
95% CI	79.1% to 95.6%				

CI: confidence interval; U.S. FDA SSED: United States Food and Drug Administration Summary of Safety and Effectiveness; TPV: Transcatheter pulmonary valve.

[a] Acceptable hemodynamic function at 6 months was defined as a mean right ventricular outflow tract gradient ≤40 mm Hg AND pulmonary regurgitant fraction <20%, without reintervention.

Subsection Summary: Food and Drug Administration-Approved Device and Indications

The evidence for the use of TPVI with the Melody valve, SAPEIN XT, and Harmony systems consists of the prospective, interventional, noncomparative pivotal studies on which each device's FDA approval was based, along with post approval registry studies and additional case series. Overall, the evidence would suggest that TPVI is associated with high rates of short-term technical success and improvements in heart failure-related symptoms and hemodynamic parameters. Studies with post procedure follow-up extending to a maximum of 7 years have suggested that the functional and hemodynamic improvements are durable, with a number of earlier devices (20% to 30%) requiring reintervention on the pulmonary valve.

Non-FDA-Approved Indications

Nonrandomized Studies

A variety of potential off-label uses of TPVI have been reported in the literature.

Data from the Valve-in-Valve International Database multicenter registry have been evaluated for the off-label use of transcatheter aortic and TPVI prostheses for tricuspid valve-in-valve implantation. (19) One hundred fifty of 156 patients in the registry had successful tricuspid valve-in-valve with a Melody (n=93) or a SAPIEN (n=57) valve. During a median 13.3-month follow-up, 22 (15%) patients died, all with NYHA class III or IV. There were 10 (6.6%) tricuspid valve reinterventions and 3 (2%) other patients who had significant recurrent dysfunction of the valve. Preintervention, 71% of patients were in NYHA class III or IV; at follow-up, 77% of surviving patients were in NYHA class I or II ($p<.001$).

A few case series have been on use of the Melody valve in patients with clinical characteristics not corresponding to FDA-approved indications. (20, 21) These indications have included the use of valves in positions other than pulmonic, patients with conduit sizes inconsistent with FDA indications, and patients with prior congenital heart repair surgery not involving the construction of an RVOT conduit. In general, these case series have reported high rates of procedural success with low rates of periprocedural complications, but longer-term outcomes are lacking.

Adverse Events

Veldurthy et al. (2025) published a meta-analysis of 4 studies of pediatric patients (N=414) evaluating the incidence of infective endocarditis following TPVR using the Melody valve. (22) The pooled incidence of infective endocarditis was 17.7% (95% CI: 3.84 to 31.55; $p<.00001$), and the average time to onset was 2.18 years post-procedure (95% CI: 0.35 to 4.01; $p<.00001$).

McElhinney et al. (2022) published an analysis of data from a multicenter registry of 2476 individuals who underwent TPV replacement with a Melody (82%) or Sapien (18%) valve between July 2005 and March 2020. (23) Patients ranged in age from 10 months to 79 years at implant (median 20.5 years). Median duration of follow-up was 2.8 years (Q1 to Q3, 0.8 to 5.4; mean: 3.4 $\pm$ 2.9 years); 29% were followed for 5 or more years and 10% for 8 or more years. A total of 95 patients died after TPV replacement, most commonly from heart failure (n=24). The cumulative incidence of death was 8.9% (95% CI, 6.9% to 11.5%) 8 years post-procedure. A total

of 258 patients underwent TPV reintervention. At 8 years, the cumulative incidence of any TPV reintervention was 25.1% (95% CI, 21.8% to 28.5%) and of surgical TPV reintervention was 14.4% (95% CI, 11.9% to 17.2%). The authors concluded that the results were comparable to outcomes of surgical conduit/valve replacement across a wide range of patient ages. A second analysis from the same registry focused on risk factors for and outcomes of endocarditis. (24) A total of 82 patients were diagnosed with endocarditis a median of 2.7 years after TPVR, for a cumulative incidence of 9.5% (95% CI, 7.9%-11.1%) at 5 years and 16.9% (95% CI, 14.2%-19.8%) at 8 years. Overall, reintervention was less often required to treat endocarditis than for other reasons, but valve explant was more often caused by endocarditis. Endocarditis was severe in 44% of patients, and 12 patients (6.6%) died, nearly all of whom were infected with Staphylococcus aureus. Younger age, a previous history of endocarditis, and a higher residual gradient were risk factors for endocarditis, but transcatheter pulmonary valve type was not.

A publication focusing on adverse events from the US Melody TPV trial was published in 2011. (25) This report assessed adverse events at a median follow-up of 30 months in 150 patients. Stent fracture occurred in 26% (39/150) of patients. The estimated freedom from stent fracture was 77% at 14 months and 60% at 39 months. Freedom from reinterventions for all patients was estimated to be 86% at 27 months, and freedom from reinterventions for patients with stent fracture was estimated at 49% at 2 years.

Boudjemline et al. (2016) conducted a prospective observational study to evaluate predictors of conduit rupture during the preparation of the RVOT for TPVI in a cohort of patients older than age 5 years with RVOT obstruction, pulmonary regurgitation, or mixed lesions, who underwent transcatheter therapies, including balloon dilatation, bare metal stent placement, or TPV placement. (26) Ninety-nine patients were included, 56 of whom were adults. Of the total cohort, 83.8% underwent Melody TPVI. Conduit rupture occurred in 9 (9.09%) patients. In 2 of the 9 patients, conduit rupture was angiographically obvious and severe with extension, causing hemodynamic instability. All conduit ruptures occurred during balloon dilatation and occurred in patients with RVOT obstruction. Heavy calcification and the presence of a homograft were associated with conduit rupture risk.

Coronary artery compression during balloon angioplasty or stent placement in the RVOT conduit is considered a relative contraindication to TPV placement. Several studies have evaluated the incidence of coronary artery compression with TPVI. Morray et al. (2013) reported on the incidence of coronary artery compression in a 4-center series of 404 patients who underwent attempted TPVI. (27) Three hundred forty-three (85%) patients underwent TPVI, and 21 (5%) patients had evidence of coronary artery compression. Most (n=19) patients with coronary artery compression did not undergo TPV placement. Fraisse et al. (2014) reported on the incidence, diagnosis, and outcome of coronary compression among patients treated with transcatheter RVOT interventions for RVOT obstruction, pulmonary regurgitation, or mixed lesions. (28) All patients underwent balloon dilatation and coronary assessment with angiography, which was followed by TPV placement if RVOT dysfunction was ongoing. Of 100 patients evaluated, 83% had implantation of a Melody TPV. Coronary artery compression occurred in 6 cases, all of which could be diagnosed by selective coronary angiogram

and/or aortic root angiogram during balloon dilation of the RVOT. No specific risk factors for coronary artery compression were identified.

Subsection Summary: Non-Food and Drug Administration-Approved Indication
For individuals who have a history of congenital heart disease and current RVOT obstruction who receive TPVI with a non-FDA-approved device or indication, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. There is limited evidence on the off-label use of TPVI including the use of a non-FDA-approved valve or use of an approved valve for a non-FDA-approved indication. The published case series enrolled relatively few patients and are heterogeneous regarding devices used and indications for TPVI. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Summary of Evidence
For individuals who have a history of congenital heart disease and current right ventricular outflow tract (RVOT) obstruction who receive transcatheter pulmonary valve implementation (TPVI) with a U.S. Food and Drug Administration (FDA) approved device and indication, the evidence includes a systematic review of retrospective comparative studies, prospective, interventional, noncomparative studies, and a multicenter registry of 2476 individuals who underwent TPV replacement with a Melody (82%) or Sapien (18%) valve between July 2005 and March 2020. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. Overall, the evidence suggests that TPVI is associated with high rates of short-term technical success and improvements in heart failure-related symptoms and hemodynamic parameters. Most valves have demonstrated competent functioning by Doppler echocardiography at 6- to 12-month follow-ups. Publications with longer follow-up have reported stent fractures in up to 26% of patients; however, most stent fractures did not require reintervention. Studies with follow-up extending to a maximum of 8 years post-procedure have suggested that the functional and hemodynamic improvements are durable. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a history of congenital heart disease and current RVOT obstruction who receive TPVI with a non-FDA-approved device or indication, the evidence includes case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related mortality and morbidity. There is limited evidence on the off-label use of TPVI including the use of a non-FDA-approved valve or use of an approved valve for a non-FDA-approved indication. The published case series enrolled relatively few patients and are heterogeneous regarding devices used and indications for TPVI. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Clinical Input from Specialty Societies and Academic Medical Centers

Clinical input supports that the following indications provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice:

- Use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation;
- Use of TPVI for individuals with native or patched RVOT with at least moderate pulmonic regurgitation;
- Use of TPVI for individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); or
- Use of TPVI for individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg).

Practice Guidelines and Position Statements

American College of Cardiology, American Heart Association, et al.

In 2018, the American College of Cardiology and American Heart Association and 6 other societies published comprehensive guidelines on the management of patients with congenital heart disease. (29) Included are recommendations for treatment of pulmonary stenosis, pulmonary regurgitation and tetralogy of Fallot (Table 7).

Table 7. ACC/AHA Guidelines on the Management of Patients with Tetralogy of Fallot

Recommendation	SOR	LOE
"Pulmonary valve replacement (surgical or percutaneous) for relief of symptoms is recommended for patients with repaired TOF and moderate or greater PR with cardiovascular symptoms not otherwise explained."	Strong	B-NR
"Pulmonary valve replacement (surgical or percutaneous) is reasonable for preservation of ventricular size and function in asymptomatic patients with repaired TOF and ventricular enlargement or dysfunction and moderate or greater PR."	Moderate	B-NR
"Surgical pulmonary valve replacement may be reasonable for adults with repaired TOF and moderate or greater PR with other lesions requiring surgical interventions."	Weak	C-EO
"Pulmonary valve replacement, in addition to arrhythmia management, may be considered for adults with repaired TOF and moderate or greater PR and ventricular tachyarrhythmia."	Weak	C-EO

ACC/AHA: American College of Cardiology/American Heart Association; B-NR: Non-randomized (moderate quality evidence); C-EO: consensus of expert opinion; LOE: level of evidence, PR: pulmonary regurgitation; SOR: strength of recommendation; TOF: tetralogy of Fallot.

Society for Cardiovascular Angiography and Interventions and the Adult Congenital Heart Association

In 2020, the Society for Cardiovascular Angiography and Interventions and the Adult Congenital Heart Association published a position statement on operator and institutional recommendations for TPVI. (30) Included were recommendations for interventional training,

practicing physician competency, ongoing education and training, and institutional and team requirements.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 8.

Table 8. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT02744677[a]	COngenital Multicenter Trial of Pulmonic vAlve Dysfunction Studying the SAPIEN 3 interventIONal THV (COMPASSION S3)	108	Jun 2031
NCT02979587[a]	The Medtronic Harmony™ Transcatheter Pulmonary Valve Clinical Study	86	Feb 2031
NCT02987387[a]	New Enrollment SAPIEN XT Post-Approval Study (COMPASSION XT PAS)	57	Sep 2025
NCT04860765[a]	Congenital Multicenter Trial of Pulmonic Valve Dysfunction Studying the SAPIEN 3 Interventional THV Post-Approval Study	150	Aug 2030
NCT05077774[a]	Harmony TPV Post-Approval Study (Harmony PAS2)	150	Mar 2035
NCT06906926[a]	Harmony TPV EMEA Post-Market Study	80	Dec 2032

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	33477
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2025	Document updated with literature review. Coverage unchanged. Added references 22 and 31.
12/15/2024	Document updated with literature review. Coverage unchanged. Reference 18 added; one removed.
01/01/2024	Document updated with literature review. Coverage unchanged. References 1, 14, 18, 22, and 23 added; others removed.
10/01/2022	Reviewed. No changes.
04/15/2022	Document updated with literature review. The following change was made to Coverage: U.S. Food and Drug Administration (FDA)-approved valve was added to the medically necessary coverage statement for patients with congenital heart disease and current right ventricular outflow tract (RVOT) obstruction or regurgitation. References 3, 4, 13, 15, 25, and 26 added; some updated and others removed.
08/15/2020	Reviewed. No changes.

11/01/2019	Document updated with literature review. Coverage revised to indicate: Transcatheter pulmonary valve implantation may be considered medically necessary for patients with congenital heart disease and current right ventricular outflow tract obstruction (RVOT) or regurgitation including the following indications: Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with at least moderate pulmonic regurgitation; OR Individuals with native or patched RVOT with at least moderate pulmonic regurgitation; OR Individuals with right ventricle-to-pulmonary artery conduit with or without bioprosthetic valve with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg); OR Individuals with native or patched RVOT with pulmonic stenosis (mean RVOT gradient at least 35 mm Hg). Transcatheter pulmonary valve implantation is considered experimental, investigational and/or unproven for all other indications. Added references 9-10, 22-23, 30, 43-44, 46, and 48.
10/15/2017	Reviewed. No changes.
04/15/2016	Document updated with literature review. Coverage unchanged.
04/15/2015	Reviewed. No changes.
08/15/2014	Document updated with literature review. Coverage unchanged.
10/15/2012	New medical document. (Transcatheter pulmonary valve implantation was previously considered experimental, investigational and unproven on SUR707.028 Transcatheter Heart Valve Replacement). The following change was made: Transcatheter pulmonary valve implantation may be considered medically necessary for patients with prior repair of congenital heart disease and right ventricular outflow tract (RVOT) dysfunction, who are not good candidates for open repair when a listed condition is met. Transcatheter pulmonary valve implantation is considered experimental, investigational and unproven for all other indications. [NOTE: A link to the medical policy titled “Transcatheter Heart Valve Replacement” can be found at the end of medical policy titled SUR707.028 Transcatheter Aortic-Valve Implantation for Aortic Stenosis]