Subject: Transcatheter Pulmonary Valve Replacement		Original Effective Date: 10/30/13
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Contents

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[2]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [3-6]

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 right ventricular outflow tract (RVOT) and pulmonary valve by means of a surgical homograft or a bovine-derived valved conduit. Over time, these repairs are disposed to the development of right ventricular outflow tract (RVOT) dysfunction leading to pulmonary regurgitation and/or stenosis. Interventions for correction of pulmonary stenosis include open heart surgery with valve replacement, balloon dilatation, or percutaneous stenting.

Treatment options for pulmonary regurgitation are surgical with reconstruction of the RVOT conduit or replacement of the pulmonary valve through open surgery. These subsequent surgical corrections could result in numerous open heart procedures throughout the lifetime of these patients.

Transcatheter pulmonary valve replacement

There are 3 primary approaches to percutaneous pulmonary valve implantation (PPVI). For the most common approach, the operator inserts the catheter through the femoral vein into the heart and the pulmonary artery (transfemoral approach). The operator might also gain access through the internal jugular vein (transjugular approach) or a small incision into the chest (transapical approach), but these approaches are less common. Once the pulmonary valve is in its correct position, the operator withdraws the protective sheath surrounding the valve, expands the balloon, and releases the valve. The catheter is then withdrawn. Fluoroscopy is used to confirm that the valve is functioning properly. PPVI takes approximately 2 to 3 hours and is performed under general anesthesia.

FDA Information: [1]

At the current time there are two percutaneous pulmonary valve implantation (PPVI) systems FDA approved: The Medtronic Melody pulmonary valve and the Edwards Sapien valve. The Medtronic Melody Transcatheter Pulmonary Valve and Medtronic Ensemble Transcatheter Valve Delivery System (Medtronic, Inc., Santa Ana, CA) received premarket approval on January 27, 2015 for the treatment of adults and children with previously implanted, poorly functioning pulmonary valve conduits. It is indicated 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 was equal to or greater than 16 mm in diameter when originally implanted and Dysfunctional Right Ventricular Outflow Tract (RVOT) conduits with a clinical indication for intervention, and either:
  - Regurgitation: $\geq$ moderate regurgitation, or
  - Stenosis: mean RVOT gradient $\geq$ 35 mmHg.

The Edwards SAPIEN XT Transcatheter Heart Valve and accessories (Edwards Lifesciences, LLC, Irvine, CA) received FDA approval for pulmonary valve use through the PMA process on February 29, 2016. The Edwards SAPIEN was originally approved for aortic valve use in 2011. Approval was based on clinical evidence from the Congenital Multicenter trial of Pulmonic valve regurgitation studying the SAPIEN Interventional (COMPASSION) THV trial. [33] According to the PMA approval order, this device is indicated for use in pediatric and adult patients with the following clinical conditions:

- A dysfunctional, non-compliant Right Ventricular Outflow Tract (RVOT) conduit with a clinical indication for intervention and either:
  - Regurgitation: $\geq$ moderate regurgitation, and/or
  - Stenosis: mean RVOT gradient $\geq$ 35 mmHg.

CLINICAL CRITERIA [1 3-6 10-51]

Transcatheter pulmonary valve implantation using a FDA approved valve (i.e. Melody or Edwards Sapien) may be considered medically necessary in children and adults when the following device specific criteria are met:

- Medtronic Melody® Transcatheter Pulmonary Valve when ALL of the following are met:
  - existence of a full (circumferential) right ventricular outflow tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted; and
  - dysfunctional RVOT conduit with a clinical indication for intervention, and EITHER of the following:
    - Regurgitation: ≥ moderate regurgitation; or
    - Stenosis: mean RVOT gradient ≥ 35 mmHg.

- Edwards SAPIEN™ XT Transcatheter Heart Valve and Accessories when ALL of the following are met:
  - dysfunctional, non-compliant RVOT conduit with a clinical indication for intervention; and EITHER of the following:
    - Regurgitation: ≥ moderate regurgitation; and/or
    - Stenosis: mean RVOT gradient ≥ 35 mmHg.

CONTRAINDICATIONS [1 3-6]

Relative or absolute contraindications for PPVI include all of the following:

- History of endocarditis or other active infection within 6 months of PPVI
- RVOT size is not appropriate for stent valve delivery (size range depends on the valve system)
- Venous occlusions that do not permit percutaneous femoral or jugular vein access
- Vessel size and characteristics in which the placement of a 22- to 24-Fr introducer sheath would not be safe
- Morphology of the RVOT does not permit a percutaneous approach
- Presence of coronary artery compression
- Weight < 30 kg

SUMMARY OF MEDICAL EVIDENCE [10-51]

Early results of the Melody U.S. Clinical Trial were published by Zahn et al. (2009). This trial was designed to evaluate the safety, procedural success, and short-term effectiveness of the Melody transcatheter pulmonary valve in patients with dysfunctional right ventricular outflow tract conduits. 34 patients underwent catheterization for intended Melody valve implantation at three centers between January and September, 2007. The mean age was 19.4 ± 7.7 years. Doppler mean gradient was 28.8 ± 10.1 mm Hg, and 94% of patients had moderate or severe pulmonary regurgitation (PR). Implantation was successful in 29 of 30 attempts, and not attempted in four patients. Complications included one conduit rupture requiring urgent surgery and device removal, one distal pulmonary artery guidewire perforation, and one instance of wide complex tachycardia. Peak systolic conduit gradient fell from 37.2 ± 16.3 mm Hg to 17.3 ± 7.3 mm Hg. None of the patients had more than mild PR. At 6-months, conduit Doppler mean gradient was 22.4± 8.1 mm Hg, and pulmonary regurgitation fraction as measured by magnetic resonance imaging was significantly improved (3.3 ± 3.6% vs. 27.6 ± 13.3%, $p<0.0001$). Stent fracture occurred in 8 of 29 implants. Three of these patients were subsequently treated with a second Melody valve for recurrent stenosis during follow-up. The authors concluded that implantation of the Melody valve for RVOT conduit dysfunction can be performed by experiences operators and appears safe, and has encouraging acute and short-term outcomes. Longer follow-up and a larger patient experience are needed to determine the ultimate role of this therapy in the treatment of conduit dysfunction. [10]

McElhinney et al. (2010) evaluated short and medium-term outcomes in the expanded Melody U.S. Trial (n=136). Implantation was attempted in 124 patients, and was achieved successfully in all except one. Placement was not attempted in the other 12 patients due to the risk of coronary artery compression (n=6) or other clinical or protocol contraindications. There was one death from intracranial hemorrhage after coronary artery dissection, and one valve was explanted after conduit rupture. The median peak RVOT gradient was 37 mm Hg prior to implantation and 12 mm Hg immediately following implantation. Pulmonary regurgitation (PR) was moderate or severe in 92 patients prior to implantation, and no patient had greater than mild PR immediately after implantation or during follow-up (≥ one year in 65 patients). Freedom from stent fracture was 77.8% ± 4.3% at 14 months, and freedom from Melody valve dysfunction or reintervention was 93.5 ± 2.4% at one year. A higher RVOT gradient at discharge and younger age were associated with shorter freedom from dysfunction. [11]

Vezmar et al. (2010) conducted a case series to evaluate the physiological and clinical consequences of percutaneous pulmonary valve implantation (PPVI) in patients with chronic right ventricular outflow tract (RVOT) obstruction and volume overload (n=28). Of 28 patients, 16 had the Melody valve implanted within a bioprosthetic valve. The procedure resulted in acute improvement in symptoms, hemodynamic status and objective findings of exercise performance. There were no acute device-related complications, with stent fractures were noted in 10.8% of patients. Early follow-up demonstrated persistent improvement in ventricular parameters, PR, and objective exercise capacity. [12]

Eiken et al. (2011) published results of 102 consecutive percutaneous pulmonary valve implantations performed at two centers in Germany between 2006 and 2010. The median patient age was 21.5 years. Sixty-one patients had undergone surgical correction of a Tetralogy of Fallot/pulmonary atresia with ventricular septal defect, and14 had a common arterial trunk; the remaining patients had been treated surgically for transposition of the great arteries (n=9) or aortic stenosis (n=8), or had a variety of other cardiac lesions (n=10). The majority of conduits (79) used during previous surgery were homografts. The median peak systolic RVOT gradient between the right ventricle and the pulmonary artery decreased immediately following the procedure from 37 mmHg (29–46 mmHg) to 14 mmHg (9–17 mmHg, p< 0.001). Pulmonary regurgitation assessed by MRI was reduced from a median of 16% (5–26%) to 1% (0–2%, p<0.001). The median end-diastolic RV-volume index also decreased significantly (p=0.001). One patient died due to compression of the left coronary artery. At a median follow-up of 357 days (99–388 days), the mean doppler gradient in the RVOT decreased from a pre-procedure median of 36 mmHg (26–44) to a median of 15 mmHg (12–20) at the latest follow-up (p<0.0001). The authors concluded that PPVI can be performed by an experienced structural heart disease interventionalist in patients with RVOT dysfunction. Medium and long term follow up needs to be assessed to document sustained benefit, however. It remains to be proved whether the improvements in hemodynamics persist, and the goal to reduce the number of cardiothoracic operations during the lifetime of the patient can be achieved. [13]

McElhinney et al. (2011) reported patient-related and procedural risk factors in the US Melody Valve Trial. From January 2007 to January 2010, 150 patients (median age, 19 years) underwent TPV implantation in the Melody valve Investigational Device Exemption trial. Existing conduit stents from a prior catheterization were present in 37 patients (25%, fractured in 12); 1 or more new pre-stents were placed at the TPV implant catheterization in 51 patients. During follow-up (median, 30 months), Melody stent fracture (MSF) was diagnosed in 39 patients. Freedom from a diagnosis of MSF was 77+/-4% at 14 months (after the 1-year

evaluation window) and 60+/-9% at 39 months (3-year window). On multivariable analysis, implant within an existing stent, new pre-stent, or bioprosthetic valve (combined variable) was associated with longer freedom from MSF (P<0.001), whereas TPV compression (P=0.01) and apposition to the anterior chest wall (P=0.02) were associated with shorter freedom from MSF. Freedom from RVOT reintervention was 86+/-4% at 27 months. Among patients with a MSF, freedom from RVOT reintervention after MSF diagnosis was 49+/-10% at 2 years. Factors associated with reintervention were similar to those for MSF. The authors concluded that MSF was common after TPV implant in this multicenter experience and was more likely in patients with severely obstructed RVOT conduits and when the TPV was directly behind the anterior chest wall and/or clearly compressed. A TPV implant site protected by a pre-stent or bioprosthetic valve was associated with lower risk of MSF and reintervention. [15]

Hasan et al. (2011) described the immediate and short-term results of Melody valves implanted in a high-pressure environment. Definitions of a high-pressure system were established for Melody valves implanted in the systemic (i.e., aortic or mitral position) and pulmonary (i.e., right ventricular outflow tract conduit or tricuspid valve annulus) circulations. Implants in these environments were ascertained from databases of the 5 centers that participated in the US Investigational Device Exemption trial. Thirty implants met the inclusion criteria: 23 pulmonary circulation implants (all in the pulmonary position) systemic circulation implants (5 in the native aortic position, 1 in a left ventricle-to-descending aorta conduit, and 1 in the mitral annulus). All pulmonary circulation implants were performed percutaneously in the catheterization laboratory. A hybrid approach (surgical exposure for transcatheter implant) was used for 4 of the aortic implants. There were no procedure-related deaths. Three patients died of nonprocedural- and nonvalve-related causes. At 1 year, freedom from moderate to severe regurgitation was 100%, and freedom from mild regurgitation was 90%. Freedom from moderate to severe stenosis was 86% at 1 year. The authors concluded that short-term performance of the Melody valve in high-pressure environments is encouraging, with good valve function in all patients. The Melody valve may provide a reasonable option for transcatheter therapy in pediatric patients who are poor candidates for surgical valve replacement in high-pressure systems. [16]

Lurtz et al. (2011) reported the results of early versus late functional outcome after successful percutaneous pulmonary valve implantation. Sixty-five patients with sustained hemodynamic effects of PPVI at 1 year were included. Patients were divided into 2 subgroups based on pre-procedural predominant pulmonary stenosis (PS) (n = 35) or predominant pulmonary regurgitation (PR) (n = 30). Data from magnetic resonance imaging and cardiopulmonary exercise testing were compared at 3 time points: before PPVI, within 1 month (early) and at 12 months (late) after PPVI. There was a significant decrease in right ventricle end-diastolic volume early after PPVI in both subgroups of patients. Right ventricle ejection fraction improved early only in the PS group (51 ± 11% vs. 58 ± 11% and 51 ± 12% vs. 50 ± 11%, $p < 0.001$ for PS, $p = 0.13$ for PR). Late after intervention, there were no further changes in magnetic resonance parameters in either group (right ventricle ejection fraction, 58 ± 11% in the PS group and 52 ± 11% in the PR group, $p = 1.00$ and $p = 0.13$, respectively). In the PS group at cardiopulmonary exercise testing, there was a significant improvement in peak oxygen uptake early (24 ± 8 ml/kg/min vs. 27 ± 9 ml/kg/min, $p = 0.008$), with no further significant change late (27 ± 9 ml/kg/min, $p = 1.00$). In the PR group, no significant changes in peak oxygen uptake from early to late could be demonstrated (25 ± 8 ml/kg/min vs. 25 ± 8 ml/kg/min vs. 26 ± 9 ml/kg/min, $p = 0.48$). The authors concluded that in patients with a sustained hemodynamic result 1 year after PPVI, a prolonged phase of maintained cardiac function is

observed. However, there is no evidence for further positive functional remodeling beyond the acute effects of PPVI. [8]

Gillespie et al (2012) reported the combined experience with transcatheter pulmonary valve implantation within Melody-in-bioprosthetic valves (BPVs) from 8 centers in the United States and discuss technical aspects of the Melody-in-BPV procedure. A total of 104 patients underwent Melody-in-BPV in the pulmonary position at 8 US centers from April 2007 to January 2012. Ten different types of BPVs were intervened on, with Melody valve implantation at the intended site in all patients. Following Melody valve implant, the peak right ventricle-to-pulmonary artery gradient decreased from 38.7 ± 16.3 to 10.9 ± 6.7 mm Hg (P<0.001), and the right ventricular systolic pressure fell from 71.6 ± 21.7 to 46.7 ± 15.9 mm Hg (P<0.001). There was no serious procedural morbidity, and no deaths related to the catheterization or implant. At a median follow-up of 12 months (1-46 months), no patients had more than mild regurgitation, and 4 had a mean right ventricular outflow tract gradient ≥30 mm Hg. During follow-up, there were 2 stent fractures, 3 cases of endocarditis (2 managed with surgical explant), and 2 deaths that were unrelated to the Melody valve. The authors concluded that Transcatheter pulmonary valve implantation using the Melody valve within BPVs can be accomplished with a high rate of success, low procedure-related morbidity and mortality, and excellent short-term results. The findings of this preliminary multicenter experience suggest that the Melody valve is an effective transcatheter treatment option for failed BPVs. [17]

Boudjemline et al (2012) evaluated the use of the Melody valve for hemodynamically significant isolated pulmonary regurgitation. Procedural and short-term outcomes data from13 patients who underwent Melody valve implantation for a large RVOT with significant pulmonary regurgitation as the primary lesion were analyzed. All procedures were successful. The mean follow-up period was 30 +/- 4 months after the procedure. There was no incidence of stent fracture, migration or embolization. Only one patient who underwent the jailing technique developed a significant paraprosthetic leak and is scheduled for redilatation of the Melody valve. The authors concluded that Careful patient selection, balloon sizing and RVOT preparation with prestenting using the Russian dolls technique and/or the PA jailing technique are required to modify the RVOT for transcatheter valve implantation. Short-term follow-up showed competent valves with no stent fracture or migration and appears promising. Wider experience with long-term outcomes may be required to standardize the procedure in such a subset of patients. [21]

Butera et al (2013) performed a prospective, observational, multi-centric survey of patients treated in Italy by using the Melody Medtronic valve by means of a web-based database registry of the Italian Society of Pediatric Cardiology (SICP). Between October 2007 and October 2010, 63 patients were included in the registry (median age: 24 years; range 11-65 years). Forty subjects were in NYHA class I-II while 23 were in NYHA class III-IV. Patients included had a history of a median three previous surgeries (range 1-5) and a median of one previous cardiac catheterization (range 0-4). A cono-truncal disease was present in 39 patients, previous Ross operation in 9, and other diagnosis in 15. Indication to valve implantation was pure stenosis in 21 patients, pure regurgitation in 12, association of stenosis and regurgitation in 30. Implantation was performed in 61 subjects (97%). Pre-stenting was performed in 85% of cases. Median procedure time was 170 minutes (range 85-360). No significant regurgitation was recorded after procedure while the trans-pulmonary gradient reduced significantly. Early major complications occurred in seven subjects (11%). One death occurred in the early post-operative period in a severely ill subject. At a median follow-up of 30 months (range 12-48 months), three

patients died due to underlying disease. Major complications occurred in six patients during follow-up (external electric cardioversion: one patient; herpes virus encephalitis: two patients; Melody valve endocarditis needing surgical explant: two patients; major fractures of the stent and need second Melody valve implantation: two patients). Freedom from valve failure at latest follow-up was 81.4% ± 9%. Early results of the SICP registry on transcatheter Melody pulmonary valve implantation show that the procedure is safe and successful. [18]

Amat-Santos et al. (2015) described the incidence, features, predisposing factors, and outcomes of prosthetic valve endocarditis (PVE) after transcatheter valve replacement, both aortic and PPVI, published from 2000 to 2013. Among 28 publications (n=60; 32 aortic valve, 28 pulmonary valve), aortic valve patients had a high risk, with mean logistic EuroSCORE of 30.4 ± 14.0. Patients in the aortic valve group received either the Sapien/Sapien XT or CoreValve devices, while all patients in the pulmonary valve group received the Melody device. Data on antibiotic prophylaxis were not detailed and in-hospital complications were only reported for aortic valve patients. Pulmonary valve patients were much younger than aortic valve patients (mean age 19 ± 6 versus 80 ± 7 years). In patients undergoing aortic valve replacement, PVE was located in the transcatheter valve in 71.9% of cases compared with 100% of cases in the PPVI group. The median time between valve replacement and infective endocarditis was 5 months (IQR, 2 to 9 months). A higher incidence of enterococci was reported in the aortic group (34.4%), while Staphylococcus aureus was most reported among the pulmonary group (29.4%). Approximately 60% of aortic valve patients with PVE were managed medically, but with valve explantation rates from 23% to 57% and in-hospital mortality of 34.4%. Seventy-five percent of pulmonary valve patients were managed surgically, with in-hospital mortality of 7.1%. [22]

Virk et al. (2015) reported clinical results from 12 observational studies (n=677) for periprocedural mortality (death within 30 days of PPVI), complications, and freedom from RVOT reintervention. A DerSimonian-Laird random-effects model was used for analysis. There were 9 studies of the Melody device, 2 of the Sapien device, and 1 of both devices. Pooled periprocedural mortality was 1.4% (95% CI, 0.7% to 2.8%), while complication rates were relatively low and included: coronary artery compression (1.2%; 95% CI, 0.6 to 2.5), pulmonary artery obstruction (1.2%; 95% CI, 0.5% to 2.6%), valve embolization (2.4%; 95% CI, 1.3% to 4.3%), and conduit rupture (2.6%; 95% CI, 1.5% to 4.3%). Conversion to open surgery occurred in 2.8% of patients (95% CI, 1.7% to 4.6%). Incidence at latest follow-up was reported for stent fracture at 12.4% (95% CI, 7.6% to 19.6%) and infective endocarditis at 4.9% (95% CI, 3.2% to 7.6%). Freedom from RVOT reintervention ranged from100% at 4 months follow-up to 70% at 70 months follow-up. [29]

The ongoing COMPASSION study [33] (Clinicaltrials.gov number NCT00676689) called “COngenital Multicenter Trial of Pulmonic VAlve Regurgitation Studying the SAPIEN InterventIONal THV” is a prospective, non-randomized, seven center study to assess the safety and effectiveness of pulmonic implantation of the SAPIEN THV in subjects with dysfunctional RVOT conduit requiring treatment for moderate or severe pulmonary regurgitation (≥3+ pulmonary regurgitation) and/or RVOT conduit obstruction (mean gradient of >=35mmHg) by TTE. This study is no longer recruiting but has 81 participants enrolled and was initially started in May of 2008 with estimated completion date of Nov, 2019. The last update was posted in Oct of 2019 at this link: https://clinicaltrials.gov/ct2/show/results/NCT00676689?view=results

Kenny et al (2018) described 3 year outcomes of COMPASSION study. Fifty-seven of the 63 eligible patients were accounted for at the 3-year follow-up visit from a total of 69 implantations in 81 enrolled patients. THV implantation was indicated for pulmonary stenosis (7.6%), regurgitation (12.7%), or both (79.7%). Twenty-two

patients (27.8%) underwent implantation of 26-mm valves, and 47 patients received 23-mm valves. Functional improvement in New York Heart Association functional class was observed in 93.5% of patients. Mean peak conduit gradient decreased from 37.5 ± 25.4 to 17.8 ± 12.4 mm Hg ($p < 0.001$), and mean right ventricular systolic pressure decreased from 59.6 ± 17.7 to 42.9 ± 13.4 mm Hg ($p < 0.001$). Pulmonary regurgitation was mild or less in 91.1% of patients. Freedom from all-cause mortality at 3 years was 98.4%. Freedom from reintervention was 93.7% and from endocarditis was 97.1% at 3 years. There were no observed stent fractures. The authors concluded that transcatheter pulmonary valve replacement using the Edwards SAPIEN THV demonstrates excellent valve function and clinical outcomes at 3-year follow-up. [37]

PROFESSIONAL SOCIETY GUIDELINES

The European Society of Cardiology (ESC) 2010 guidelines for the management of adult congenital heart disease endorsed by the Association for European Pediatric Cardiology (AEPC) [14] include the following exclusion criteria for percutaneous pulmonic valve implantation (PPVI):

- Evidence of risk of coronary compression by the expanded implant as determined by balloon testing
- Central vein occlusion or significant obstruction
- Active infection (such as endocarditis) or high risk of infection (such as intravenous drug abuse)
- Surgery is preferred when additional interventions are considered such as tricuspid annuloplasty, coronary artery bypass, or arrhythmia surgery

The European Society of Cardiology (ESC)/Association for European Pediatric Cardiology (AEPC) 2010 guidelines [14] for the management of adult congenital heart disease include the following indications for surgical intervention or PPVI in patients with right ventricular to pulmonary artery conduits:

- Intervention is recommended in symptomatic patients with RV systolic pressure >60 mmHg (TR velocity >3.5 m/s; may be lower in cases with reduced flow) and/or moderate to severe pulmonic regurgitation.
- Intervention is suggested in asymptomatic patients with severe right ventricular outflow tract obstruction and/or severe pulmonic regurgitation when at least one of the following criteria is present:
  - Decrease in exercise capacity on cardiopulmonary exercise testing
  - Progressive RV dilation
  - Progressive RV systolic dysfunction
  - Progressive TR (at least moderate)
  - RV systolic pressure >80 mmHg (TR velocity >4.3 m/s)
  - Sustained atrial/ventricular arrhythmias

National Institute for Health and Care Excellence (NICE): A guidance entitled "Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction" was published in 2013. This guidance indicates that the evidence on percutaneous pulmonary valve implantation (PPVI) for right ventricular outflow tract (RVOT) dysfunction shows good short-term efficacy. There is little evidence on long-term efficacy but it is well documented that these valves may need to be replaced in the longer term. With regard to safety there are well-recognized complications, particularly stent fractures in the longer term, which may or may not have clinical effects. Patients having this procedure are often in poor health and might otherwise need open heart surgery (typically re-operative) with its associated risks. The procedure should be performed only in specialist units and

with arrangements in place for cardiac surgical support in the event of complications. Patient selection should be carried out by a multidisciplinary team including a cardiologist with a special interest in congenital heart disease, an interventional cardiologist and a cardiothoracic surgeon with a special interest in congenital heart disease. Additionally, this is a technically challenging procedure that should only be performed by clinicians with training and experience in interventional cardiology and congenital heart disease. [7]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
I09.89	Other specified rheumatic heart diseases
I37-I37.0	Pulmonary valve disorders
Q20.5	Discordant atrioventricular connection
Q21.3	Tetralogy of Fallot
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q22.3	Other congenital malformations of pulmonary valve
T82.01XA-T82.09XA	Breakdown (mechanical) of heart valve prosthesis; Other mechanical complication of heart valve prosthesis, initial encounter
T82.87A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter
Z95.2	Presence of prosthetic heart valve

RESOURCE REFERENCES

Government Agency

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Other Resources

52. Advanced Medical Review (AMR):
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REVIEW/REVISION HISTORY

10/30/13: New Policy
12/16/15: Policy reviewed, no changes
11/16: Policy was reviewed and updated and no changes were made to the criteria. The medical evidence summary and reference sections were updated.
9/19/17: Policy reviewed, no changes
7/10/18: Policy reviewed, no changes

12/10/19: Policy reviewed and updated with inclusion of the Edwards Sapien XT Transcatheter Heart Valve FDA approval. Updated description of PPVI procedure, revised coverage criteria to include device specific criteria, updated contraindications section, added new references and clinical trial information and updated guideline information.
12/9/20: Policy reviewed no changes to criteria based on updated literature search. Added new references.