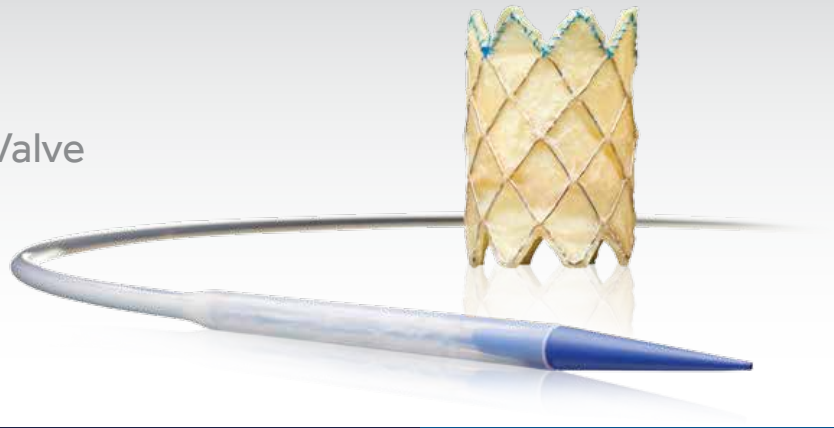


Melody®

Transcatheter Pulmonary Valve

Ensemble®

Transcatheter  
Valve Delivery System



**2016**  
**COMMONLY**  
**BILLED**  
**CODES**

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COMMONLY  
BILLED  
CODES

2016

# FOR RIGHT VENTRICULAR OUTFLOW TRACT CONDUIT DYSFUNCTION

The Medtronic Melody® Transcatheter Pulmonary Valve is used to treat patients with congenital heart defects who previously had a surgical conduit created between their right ventricle and

pulmonary artery (RV/PA) and are now experiencing conduit dysfunction of their right ventricular outflow tract.

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# HOSPITAL INPATIENT CODING AND REIMBURSEMENT

**FY2016 (EFFECTIVE  
OCTOBER 01, 2015 TO  
SEPTEMBER 30, 2016)**

## ICD-10 PCS PROCEDURE CODES

Effective October 01, 2015, hospitals use ICD-10- PCS procedure codes for inpatient admissions.

### Select ICD-10 PCS Codes

**Note:** Most of the ICD-9-CM codes can convert to many more ICD-10-PCS codes than are shown here. The ICD-10-PCS codes shown are those that reflect the typical procedure, using known Medtronic devices where appropriate. Theoretical possibilities are not shown, eg. approaches that are not common, device types that are not currently on the market.

The general equivalence between ICD-9 diagnosis and procedure codes and ICD-10 CM and PCS codes shown here is for illustrative purposes. Please refer to clinical documentation for appropriate ICD-10 code selection.

## TRANSCATHETER PULMONARY VALVE PROCEDURE CODES

ICD-9-CM Procedure Codes <sup>1</sup>	ICD-9-CM Procedure Code Description	Potential Equivalent ICD-10 PCS Procedure Code	ICD-10-PCS Procedure Code Description
35.07	Endovascular replacement of pulmonary valve	02RH37Z	Replacement of Pulmonary Valve with Autologous Tissue Substitute, Percutaneous Approach
		02RH38Z*	Replacement of Pulmonary Valve with Zooplastic Tissue, Percutaneous Approach
		02RH3JZ	Replacement of Pulmonary Valve with Synthetic Substitute, Percutaneous Approach
		02RH3KZ	Replacement of Pulmonary Valve with Nonautologous Tissue Substitute, Percutaneous Approach

\*Suggested code for Melody

## TRANSCATHETER PULMONARY VALVE DRGs

MS- DRG	Description	FY16 Medicare National Average <sup>2</sup>
266	Endovascular Cardiac Valve Replacement with MCC	\$50,772
267	Endovascular Cardiac Valve Replacement without MCC	\$38,720

MCC = Major Complication or Comorbidity

1. 2015 ICD-9 CM for hospitals, volume 1,2 & 3/ Carol J. Buck. Professional ed.

2. FY16 Medicare inpatient rates based on FY16 Final Rule issued July 31, 2015; available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html>

## CPT® PROCEDURE CODES

Physicians use CPT codes for services and hospitals use CPT for outpatient services. Relative Value Units (RVUs) present a mechanism for calculating payment. For carrier-priced codes, the carrier establishes RVUs and payment amounts on an individual case basis following review of documentation such as an operative report.

### *Valve Replacement (Coding option effective January 01, 2016)*

A new category I CPT® code was implemented on January 1, 2016.

New Code Effective January 01, 2016 for transcatheter implantation of pulmonic heart valve.	33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	2016 Total Facility RVUs	2016 Medicare Ntl Pymt <sup>3</sup>
			37.57	\$1,345

### Included In the Procedure:

- Code 33477 includes the work, when performed, of percutaneous access, placing the access sheath, advancing the repair device delivery system into position, repositioning the device as needed, and deploying the device(s). Angiography, radiological supervision, and interpretation performed to included in the code.
- Code 33477 includes all cardiac catheterization(s), intraprocedural contrast injection(s), fluoroscopic radiological supervision and interpretation, and imaging guidance performed to complete the pulmonary valve procedure. Do not report 33477 in conjunction with 76000, 76001, 93451, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93530, 93531, 93532, 93533, 93563, 93566, 93567, 93568 for angiography intrinsic to the procedure.
- Code 33477 includes percutaneous balloon angioplasty of the conduit/treatment zone, valvuloplasty of the pulmonary valve conduit, and stent deployment within the pulmonary conduit or an existing bioprosthetic pulmonary valve, when performed. Do not report 33477 in conjunction with 37236, 37237, 92997, 92998 for pulmonary artery angioplasty/valvuloplasty or scenting within the prosthetic valve delivery site.

### Separately Reportable:

- Codes 92997, 92998 may be reported separately when pulmonary artery angioplasty is performed at a site separate from the prosthetic valve delivery site.
- Codes 37236, 37237 may be reported separately when pulmonary artery scenting is performed at a site separate from the prosthetic valve delivery site.

### Other Procedures:

- Diagnostic right heart catheterization and diagnostic coronary angiography codes (93451, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93530, 93531, 93532, 93533, 93563, 93566, 93567, 93568) should not be used with 33477 to report:
  1. Contrast injections, angiography, roadmapping, and/or fluoroscopic guidance for the TPVI,
  2. Pulmonary conduit angiography for guidance of TPVI, or
  3. Right heart catheterization for hemodynamic measurements before, during, and after TPVI for guidance of TPVI.

3. CY16 Payment calculated with the Conversion Factor (CF)35.8043 from the CY 2016 Medicare Physician Fee Schedule Final Rule. Available at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-28005.pdf> and subsequent correction January 2016.

- Diagnostic right and left heart catheterization codes (93451, 93452, 93453, 93456, 93457, 93458, 93459, 93460, 93461, 93530, 93531, 93532, 93533), diagnostic coronary angiography codes (93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93563, 93564), and diagnostic pulmonary angiography code (93568) may be reported with 33477, representing separate and distinct services from TPVI, if:
  1. No prior study is available and a full diagnostic study is performed, or
  2. A prior study is available, but as documented in the medical record:
    - a. There is inadequate visualization of the anatomy and/or pathology, or
    - b. The patient's condition with respect to the clinical indication has changed since the prior study, or
    - c. There is a clinical change during the procedure that requires new evaluation.
- Other cardiac catheterization services may be reported separately when performed for diagnostic purposes not intrinsic to TPVI.
- For same session/same day diagnostic cardiac catheterization services, report the appropriate diagnostic cardiac catheterization code(s) appended with modifier 59 to indicate separate and distinct procedural services from TPVI.
- Diagnostic coronary angiography performed at a separate session from an interventional procedure may be separately reportable, when performed.
- Percutaneous coronary interventional procedures may be reported separately, when performed.
- Percutaneous pulmonary artery branch interventions may be reported separately, when performed.
- When transcatheter ventricular support is required in conjunction with TPVI, the appropriate code may be reported with the appropriate percutaneous ventricular assist device (VAD) procedure codes (33990, 33991, 33992, 33993), extracorporeal membrane oxygenation (ECMO) or extracorporeal life support services (ECLS) procedure codes (33946-33989), or balloon pump insertion codes (33967, 33970, 33973).
- When cardiopulmonary bypass is performed in conjunction with TPVI, code 33477 may be reported with the appropriate add-on code for percutaneous peripheral bypass (33367), open peripheral bypass (33368), or central bypass (33369).

## HOSPITAL OUTPATIENT CODING AND REIMBURSEMENT

## MEDICARE AMBULATORY PAYMENT CLASSIFICATIONS (APCs)

Medicare pays for hospital outpatient procedures separately via APCs. Hospital outpatient services are identified using the CPT Level I HCPCS codes. These CPT codes are grouped to one of approximately 800 different APCs.

Effective January 01, 2016:

The category I CPT code (33477) for endovascular replacement of pulmonic valve has no APC assignment because this code is on Medicare's Inpatient Only list. This means that Medicare will only reimburse for the procedure in the inpatient setting for Medicare beneficiaries. Site of service determination is the responsibility of the clinician relative to the patient's clinical condition.

### Private Payers

Private payers use various payment mechanisms such as APCs, percent of charge, carve out, fee schedule etc.

Private payers may or may not follow Medicare. Working with private payers during the pre-certification/ pre-authorization process may provide insight on how the specific payer intends to adjudicate the claim for reimbursement.

## TRANSCATHETER PULMONARY VALVE POTENTIAL DIAGNOSIS CODES

ICD-9-CM Diagnosis Codes	ICD-9-CM Procedure Code Description	Potential Equivalent ICD-10 CM Diagnosis Code	ICD-10 CM Procedure Code Description
424.3	Pulmonary valve disorders (insufficiency, stenosis, regurgitation)	I37.0	Non-rheumatic pulmonary valve stenosis
		I37.1	Non-rheumatic pulmonary valve insufficiency (regurgitation)
		I37.2	Non-rheumatic pulmonary valve stenosis with insufficiency
		I37.8	Other non-rheumatic pulmonary valve disorders
		I37.9	Non-rheumatic pulmonary valve disorder, unspecified
745.0	Common truncus	Q20.0	Common arterial trunk
745.10	Complete transposition of great vessels	Q20.3	Discordant ventriculoarterial connection
745.11	Double outlet right ventricle	Q20.1	Double outlet right ventricle
745.12	Corrected transposition of great vessels	Q20.5	Discordant atrioventricular connection
745.19	Other transposition of great vessels	Q20.2	Double outlet left ventricle
		Q20.8	Other congenital malformations of cardiac chambers and connections
745.2	Tetralogy of Fallot	Q21.3	Tetralogy of Fallot
746.00	Congenital pulmonary valve anomaly, unspecified	Q22.3	Other congenital malformations of pulmonary valve
746.01	Pulmonary valve atresia, congenital	Q22.0	Pulmonary valve atresia (congenital)
746.02	Pulmonary valve stenosis, congenital	Q22.1	Congenital pulmonary valve stenosis
746.09	Other congenital anomaly of pulmonary valve	Q22.2	Congenital pulmonary valve insufficiency
		Q22.3	Other congenital malformations of pulmonary valve
746.1	Tricuspid atresia and stenosis, congenital	Q22.4	Congenital tricuspid stenosis (atresia)
—	—	Q22.8	Other congenital malformations of tricuspid valve
		Q22.9	Congenital malformation of tricuspid valve, unspecified
746.3	Congenital stenosis of aortic valve	Q23.0	Congenital stenosis of aortic valve (atresia)
746.4	Congenital insufficiency of aortic valve	Q23.1	Congenital insufficiency of aortic valve (bicuspid valve)
746.5	Congenital mitral stenosis	Q23.2	Congenital mitral stenosis (atresia)
746.6	Congenital mitral insufficiency	Q23.3	Congenital mitral insufficiency

## TRANSCATHETER PULMONARY VALVE POTENTIAL DIAGNOSIS CODES - CONTINUED

ICD-9-CM Diagnosis Codes	ICD-9-CM Procedure Code Description	Potential Equivalent ICD-10 CM Diagnosis Code	ICD-10 CM Procedure Code Description
996.02	Mechanical complication due to heart valve prosthesis	T82.01xA	Breakdown (mechanical) of <i>heart valve</i> prosthesis, initial encounter
		T82.02xA	Displacement of heart valve prosthesis, initial encounter
		T82.03xA	Leakage of heart valve prosthesis, initial encounter
		T82.09xA	Other mechanical complication of heart valve prosthesis, initial encounter
		T82.221A	Breakdown (mechanical) of <i>biological heart valve graft</i> , initial encounter
		T82.222A	Displacement of biological heart valve graft, initial encounter
		T82.223A	Leakage of biological heart valve graft, initial encounter
		T82.228A	Other mechanical complication of biological heart valve graft, initial encounter
996.09	Mechanical complication of device, implant, and graft, other	T82.518A	Breakdown (mechanical) of other cardiac and vascular devices and implants, initial encounter
		T82.538A	Leakage of other cardiac and vascular devices and implants, initial encounter
		T82.598A	Other mechanical complication of other cardiac, and vascular devices and implants, initial encounter
996.71	Other complication due to heart valve prosthesis	T82.817A	Embolism of cardiac prosthetic devices, implants and grafts, initial encounter
		T82.827A	Fibrosis of cardiac prosthetic devices, implants and grafts, initial encounter
		T82.837A	Hemorrhage of cardiac prosthetic devices, implants, grafts, initial encounter
		T82.847A	Pain from cardiac prosthetic devices, implants and grafts, initial encounter
996.72	Other complication due to other cardiac device, implant and graft (including coronary artery bypass graft)	T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter
		T82.867A	Thrombosis of cardiac prosthetic devices, implants, grafts, initial encounter
		T82.897A	Other specified complication of cardiac prosthetic devices, implants and grafts, initial encounter
V13.69	Personal history of other (corrected) congenital malformations	Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system
V42.2	Heart valve replaced by transplant	Z95.3	Presence of xenogenic heart valve (transplant)
		Z95.4	Presence of other heart valve replacement
V43.3	Heart valve replaced by other means	Z95.2	Presence of prosthetic heart valve (mechanical)
V53.39	Fitting and adjustment of other cardiac device	Z45.09	Encounter for adjustment and management of other cardiac device



## Brief Statement for:

### Melody® Transcatheter Pulmonary Valve Ensemble® Transcatheter Valve Delivery System Important Labeling Information for United States

#### Indications

The Melody TPV 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 RVOT conduits with a clinical indication for intervention, AND:
  - regurgitation:  $\geq$  moderate regurgitation, AND/OR
  - stenosis: mean RVOT gradient  $\geq$  35 mm Hg

#### Contraindications

None known.

#### Warnings/Precautions/Side Effects

- **DO NOT implant in the aortic or mitral position. Preclinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22-Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.

- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture,\* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

\* The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions For Use provided with the product.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

The Medtronic CardioVascular Coding Hotline is available to respond to your coding questions at 866-616-8400.

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