

2015

Melody® Transcatheter Pulmonary Valve and
Ensemble® Transcatheter Valve Delivery System

**COMMONLY
BILLED
CODES** | **2015**

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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 dysfunction of their right ventricular outflow tract.

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Medtronic provides this information for your convenience only. It is not intended as a recommendation regarding clinical practice.

ICD-9-CM Diagnosis Codes¹

Diagnosis codes are used by both physicians and hospitals to document the indication for the procedure. The diagnosis code assigned depends on the specific indication for implanting the Melody® Valve.

Pulmonary Transcatheter Valve Potential Diagnosis Codes		
Scenario	ICD-9-CM Diagnosis Code ¹	Description
If the active condition is the failed conduit, the code depends on the type of conduit complication. The mechanical complication codes include valve leakage and conduit failure without specificity. The other complication codes include stenosis of the conduit.	996.02	Mechanical complication due to heart valve prosthesis
	996.09	Mechanical complication of cardiac device, implant, and graft, other
	996.71	Other complication due to heart valve prosthesis
	996.72	Other complication of other cardiac device implant or graft
For continuing treatment of the underlying clinical disorder which is still present, the underlying disorder is coded.	424.3	Pulmonary valve disorders
	745.0	Common truncus
	745.1X	Transposition of great vessels
	745.2	Tetralogy of Fallot
	746.0X	Congenital anomalies of pulmonary valve
	747.3	Congenital anomalies of pulmonary artery
V codes are used to show the patient's history of the congenital anomaly as well as prior surgery. These codes are used as secondary diagnosis codes.	V13.69	Personal history of other (corrected) congenital malformations
	V15.1	Personal history of surgery to heart and great vessels

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Hospital Inpatient Coding and Reimbursement

FY2015 (Effective October 01, 2014 to September 30, 2015)

ICD-9-CM Procedure Codes

Hospitals use ICD-9 procedure codes for inpatient admissions. On August 01, 2011 CMS finalized new procedure code 35.07 for endovascular replacement of pulmonic valve effective October 01, 2011.

Note: ICD-9-CM procedure codes expire September 30, 2015. Use appropriate ICD-10 CM codes effective October 01, 2015. Sample ICD-10 CM codes are provided at the end of this document for illustration.

Valve Replacement (Effective October 01, 2011)

ICD-9-CM Procedure Code	Description
35.07	Endovascular replacement of pulmonic valve

Note: The reimbursement rates shown below reflect Medicare's prospective payment systems. Other payers may use these systems or variations on them for patients outside the Medicare population. Contact the individual payers for their specific payment methodologies.

MS- DRG	Description	FY15 Medicare National Average ²
266	Endovascular Cardiac Valve Replacement with MCC	\$52,809
267	Endovascular Cardiac Valve Replacement without MCC	\$39,651

MCC = Major Complication or Comorbidity

CC = Complication or Comorbidity

Physician Coding and Reimbursement²

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 July 01, 2011)

A category III CPT® code was implemented on July 1, 2011. Category III codes are all carrier-priced.

New Code Effective July 01, 2011 for transcatheter implantation of pulmonic heart valve.	0262T	Implantation of catheter-delivered prosthetic pulmonary valve, endovascular approach	Carrier Priced ³
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Included in procedure:

- Congenital cardiac catheterization(s)
- Intraprocedural contrast injection(s)
- Fluoroscopic radiological supervision and interpretation
- Imaging guidance when performed to complete the pulmonary valve procedure
- Percutaneous balloon angioplasty/valvuloplasty of the pulmonary valve/conduit
- Stent deployment within the pulmonary conduit

Separately reportable:

- Cardiovascular stent placement in separate site other than the prosthetic valve delivery site
- Pulmonary artery angioplasty performed at a separate site from the prosthetic valve delivery site

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 July 01, 2011:

The category III CPT code (0262T) 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.

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.

Pulmonary Transcatheter Valve Procedure Codes			
ICD-9-CM Procedure Codes	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 Zooplasic Tissue, Percutaneous Approach
		02RH3JZ	Replacement of Pulmonary Valve with Synthetic Substitute, Percutaneous Approach
		02RH3KZ	Replacement of Pulmonary Valve with Nonautologous Tissue Substitute, Percutaneous Approach

Selected ICD-10 CM Codes

Pulmonary Transcatheter Valve Potential Diagnosis Codes			
ICD-9-CM Diagnosis Codes	ICD-9-CM Diagnosis Code Description	Potential Equivalent ICD-10 CM Diagnosis Code	ICD-10 CM Diagnosis Code Description
996.02	Mechanical complication due to heart valve prosthesis	T82.21xA	Breakdown (mechanical) of biological heart valve graft, initial encounter
		T82.23xA	Leakage of biological heart valve graft, initial encounter
		T82.29xA	Other mechanical complication of biologic heart valve graft, initial encounter
996.09	Mechanical complication of cardiac 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

Pulmonary Transcatheter Valve Potential Diagnosis Codes (continued)

ICD-9-CM Diagnosis Codes	ICD-9-CM Diagnosis Code Description	Potential Equivalent ICD-10 CM Diagnosis Code	ICD-10 CM Diagnosis Code Description
996.71	Other complication due to heart valve prosthesis	T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts
		T82.897A	Other specified complication of cardiac prosthetic devices, implants and grafts
996.72	Other complication of other cardiac device implant or graft	T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts
		T82.897A	Other specified complication of cardiac prosthetic devices, implants and grafts
424.3	Pulmonary valve disorders	I37.0	Nonrheumatic pulmonary valve stenosis
		I37.1	Nonrheumatic pulmonary valve insufficiency
		I37.2	Nonrheumatic pulmonary valve stenosis with insufficiency
		I37.8	Other nonrheumatic pulmonary valve disorders
745.0	Common truncus	Q20.0	Common arterial trunk
745.1X	Transposition of great vessels	Q20.1	Double outlet right ventricle
		Q20.3	Discordant ventriculoarterial connection
		Q20.5	Discordant atrioventricular connection
745.2	Tetralogy of Fallot	Q21.3	Tetralogy of Fallot
746.0X	Congenital anomalies of pulmonary valve	Q22.0	Pulmonary valve atresia
		Q22.1	Congenital pulmonary valve stenosis
		Q22.2	Congenital pulmonary valve insufficiency
		Q22.3	Other congenital malformations of pulmonary valve
747.3x	Congenital anomalies of pulmonary artery	Q25.5	Atresia of pulmonary artery
		Q25.6	Stenosis of pulmonary artery
		Q25.71	Coarctation of pulmonary artery
		Q25.72	Congenital pulmonary arteriovenous malformation
		Q25.79	Other congenital malformations of pulmonary artery
V13.69	Personal history of other (corrected) congenital malformations	Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system
V15.1	Personal history of surgery to heart and great vessels	Z98.89	Other specified postprocedural states
		Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system

Melody TPV Coding Guide Footnotes

1. 2015 ICD-9 CM for hospitals, volume 1,2 & 3/ Carol J. Buck. Professional ed.
2. The FY2015 payment amounts indicated are estimates only based upon data elements derived from various CMS sources. These sources include CMS-1607-F, released 8/4/14 and corrections released 9/30/14, and the hospital payment impact file dated 9/30/14. Calculations assume that all hospitals are receiving the full 1.7% quality reporting update. Actual payment may vary based on various hospital-specific factors not reflected in the source data. Actual payment may also vary based on adjustments that CMS may make from time to time.
3. Status Indicator C = Carrier priced code. Carriers will establish RVUs and payment amounts for these services, generally on a case by case basis following review of documentation, such as operative report. 69 Federal Register #219, November 15, 2004.

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**.

Important Labeling Information for Geographies Outside of the United States

Indications

The Melody® Transcatheter Pulmonary Valve is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic Right Ventricular Outflow Tract (RVOT) conduits with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting.
- Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted.

The intended lifetime for the Melody® device is 2 years.

Contraindications

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath; Implantation in left heart;
- Unfavorable right ventricular outflow tract for good stent anchorage;
- Severe right ventricular outflow obstruction, which cannot be dilated by balloon;
- Obstruction of the central veins;
- Clinical or biological signs of infection;
- Active endocarditis;
- Known allergy to aspirin or heparin;
- Pregnancy.

Potential Complications / Adverse Events

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, pain at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: 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.

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

The Melody® Transcatheter Pulmonary Valve and Ensemble® Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe. Additionally, a Medical Device Licence has been granted and the system is available for distribution in Canada.

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