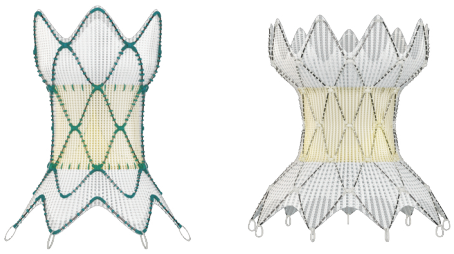
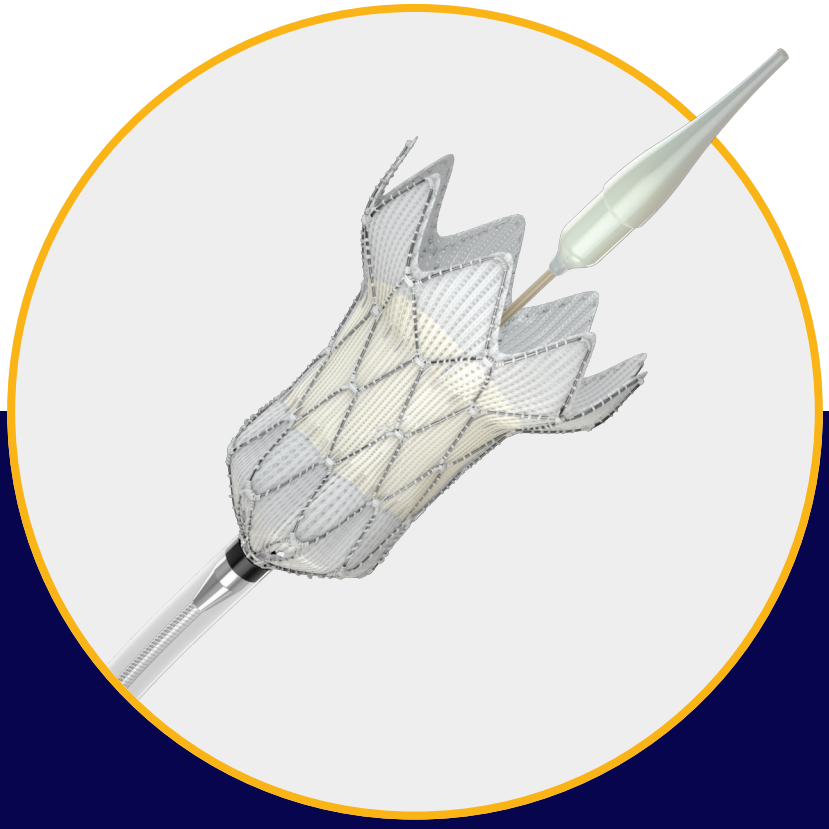
Medtronic

Harmony™

Transcatheter Pulmonary Valve





2026 Commonly Billed Codes

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Commonly billed codes

2026

For right ventricular outflow tract dysfunction

The Harmony™ transcatheter pulmonary valve (TPV) system 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 ≥ 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.

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The provider has the responsibility to determine medical necessity and to submit appropriate documentation, codes, and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, and/or legal counsel for interpretation of coding, coverage, and payment policies and any applicable laws or regulations that may apply.

This document provides assistance for FDA-approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g., instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related service.

Hospital inpatient coding and reimbursement

FY2026 (Effective October 1, 2025 to September 30, 2026)

ICD-10 PCS procedure code

Hospitals use ICD-10 PCS codes for inpatient procedures. They are a factor in Medicare DRG payment for hospital inpatient services.

Note: The ICD-10 PCS code shown reflects the typical procedure, using known Medtronic devices where appropriate. Theoretical possibilities are not shown, e.g., approaches that are not common and device types that are not currently on the market.

Transcatheter pulmonary valve procedure code

ICD-10 PCS procedure code[1]	ICD-10 PCS procedure code description
02RH38M	Replacement of pulmonary valve with zooplastic tissue, native site, percutaneous

Transcatheter pulmonary valve DRGs

MS-DRG	Description	FY26 Medicare National Average Payment[2]
266	Endovascular cardiac valve replacement and supplement procedures with MCC	$44,595
267	Endovascular cardiac valve replacement and supplement procedures without MCC	$34,653

MCC = major complication or comorbidity

Physician coding and reimbursement

CPT®* procedure codes

Physicians use CPT codes for services and hospitals. Relative value units (RVUs) are used to calculate payment under Medicare's RBRVS system for physician payment review of documentation, such as an operative report.

CY 2026 payment was calculated with the conversion factor (CF) of $33.40. CMS may make adjustments to any or all of the data inputs from time to time without notice.

CPT code	Description	2026 Total Facility RVUs	2026 Medicare National Unadjusted Payment[3]
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed	33.71	$1,126

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 guide TPVI (e.g., guiding device placement and documenting completion of the intervention) are 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, 93451, 93453, 93454, 93455, 93456, 93457, 93458, 93459, 93460, 93461, 93563, 93566, 93567, 93568, 93569, 93573, 93593, 93594, 93596, 93597, 93598 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 stenting 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 stenting is performed at a site separate from the prosthetic valve delivery site.

Other procedures:

- Diagnostic right heart catheterization and diagnostic coronary angiography codes can be reported with 33477 only when they represent a fully diagnostic study, such as when no prior study is available or new evaluation is needed due to inadequate visualization or clinical change.
- 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, 33995, 33997), 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)

Hospitals use CPT for outpatient procedures, which Medicare reimburses using APCs.

CPT code (33477) for endovascular replacement of pulmonic valve has no APC assignment because this code is on Medicare's "inpatient-only" list. Medicare will only reimburse for the procedure in the inpatient setting. 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-10 CM diagnosis code[4]	ICD-10 CM code description
Q20.1	Double outlet right ventricle
Q20.3	Discordant ventriculoarterial connection
Q20.5	Discordant atrioventricular connection
Q21.3	Tetralogy of Fallot
Q22.0	Pulmonary valve atresia
Q22.1	Congenital pulmonary valve stenosis
Q22.2	Congenital pulmonary valve insufficiency
Q25.5	Atresia of pulmonary artery
Q25.72	Congenital pulmonary arteriovenous malformation
Q25.79	Other congenital malformations of pulmonary artery

1. 2025 ICD-10 PCS American Medical Association.
2. FY26 IPPS Final Rule Home Page. Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page. Accessed on November 23, 2025.
3. CY 2026 payment was calculated with the Conversion Factor (CF) of $33.40. CMS CY 2026 Medicare Physician Fee Schedule Final Rule. Available at: https://www.federalregister.gov/public-inspection/current. Accessed on November 20, 2025.
4. 2025 ICD-10 CM American Medical Association.

Harmony™ Transcatheter Pulmonary Valve System
Important Labeling Information for the United States

Indications: The Harmony Transcatheter Pulmonary Valve (TPV) System 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 ≥ 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.
Contraindications: The following are contraindications for the use of this device: Active bacterial endocarditis or other active infections; known intolerance to Nitinol (titanium or nickel) or an anticoagulation/antiplatelet regimen.
Warnings: General Implantation of the Harmony TPV system should be performed only by physicians who have received Harmony TPV system training. The transcatheter pulmonary valve (TPV) is to be used only in conjunction with the Harmony delivery catheter system (DCS). This procedure should only be performed where emergency pulmonary valve surgery can be performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: It has been dropped, damaged, or mishandled in any way or if the Use By date has elapsed.
Transcatheter pulmonary valve (TPV) This device was designed for single use only. Do not reuse, reprocess, or resterilize the TPV. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not resterilize the TPV by any method. Exposure of the device and container to irradiation, steam, ethylene oxide, or other chemical sterilants renders the device unfit for use. The device is packaged with a temperature sensor. Do not freeze the device. Do not expose the device to extreme temperatures. Do not use the device if the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. Do not use the device if any of the following have occurred: The tamper-evident seal is broken. The serial number tag does not match the container label. The arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. The device is not completely covered by the storage solution. Do not contact any of the Harmony TPV system components with cotton or cotton swabs. Do not expose any of the Harmony TPV system components to organic solvents, such as alcohol. Do not introduce air into the catheter. Do not expose the device to solutions other than the storage and rinse solutions. Do not add or apply antibiotics to the device, the storage solution, or the rinse solution. Do not allow the device to dry. Maintain tissue moisture with irrigation or immersion. Do not attempt to repair a damaged device. Do not handle the valve leaflet tissue or use forceps to manipulate the valve leaflet tissue. Do not attempt to recapture the device once deployment has begun. Do not attempt to retrieve the TPV if any one of the outflow TPV struts is protruding from the capsule. If any one of the outflow TPV struts has deployed from the capsule, the TPV must be released from the catheter before the catheter can be withdrawn. Do not attempt post-implant balloon dilatation (PID) of the TPV during the procedure, which may cause damage to or failure of the TPV leading to injury to the patient resulting in reintervention. Delivery Catheter System (DCS) This device was designed for single use only. Do not reuse, reprocess, or resterilize the DCS. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reuse or resterilize the DCS. If resistance is met, do not advance the guidewire, DCS, or any other component without first determining the cause and taking remedial action. Do not remove the guidewire from the DCS at any time during the procedure.
Precautions: General Clinical long-term durability has not been established for the Harmony TPV. Evaluate the TPV performance as needed during patient follow-up. The safety and effectiveness of Harmony TPV implantation in patients with pre-existing prosthetic heart valve or prosthetic ring in any position has not been demonstrated. The Harmony TPV system has not been studied in female patients of child-bearing potential with positive pregnancy. Before Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (for a minimum of 15 minutes) and seek medical attention immediately. The TPV and the glutaraldehyde storage solution are sterile. The outside of the TPV container is nonsterile and must not be placed in the sterile field. The TPV and DCS should be used only in a sterile catheterization laboratory (cath lab) environment. Ensure that sterile technique is used at all times. Strictly follow the TPV rinsing procedure. For TPV 25: Ensure that all green sutures have been removed from the attachment suture loops on the TPV before loading onto the DCS. Prevent contamination of the TPV, its storage solution, and the DCS with glove powder. Verify the orientation of the TPV before loading it onto the DCS. The inflow end of the TPV with attachment suture loops must be loaded first. Do not place excessive pressure on the TPV during loading. Inspect the sealed DCS packaging before opening. If the seal is broken or the packaging has been damaged, sterility cannot be assured. Proper functioning of the DCS depends on its integrity. Use caution when handling the DCS. Damage may result from kinking, stretching, or forceful wiping of the DCS. This DCS is not recommended to be used for pressure measurement or delivery of fluids. Carefully flush the DCS and maintain tight DCS connections to avoid the introduction of air bubbles.
During Use The TPV segment is rigid and may make navigation through vessels difficult. Do not advance any portion of the DCS under resistance. Identify the cause of resistance using fluoroscopy and take appropriate action to remedy the problem before continuing to advance the DCS. Careful management of the guidewire is recommended to avoid dislodgement of the TPV during DCS removal. Once deployment is initiated, retrieval of the TPV from the patient is not recommended. Retrieval of a partially deployed valve may cause mechanical failure of the delivery catheter system or may cause injury to the patient. Refer to section below for a list of potential adverse events associated with the Harmony TPV implantation. During deployment, the DCS can be advanced or withdrawn prior to the outflow struts protruding from the capsule. Once the TPV struts contact the anatomy during deployment, it is not recommended to reposition the device. Advancing the catheter forward once the TPV struts make contact with the anatomy may lead to an undesired deployment or may cause damage to or failure of the TPV and injury to the patient. Refer to section below for a list of potential adverse events associated with the Harmony TPV implantation. Physicians should use judgment when considering repositioning of the TPV (for example, using a snare or forceps) once deployment is complete. Repositioning the bioprosthesis is not recommended, except in cases where imminent serious harm or death is possible (for example, occlusion of the main, left, or right pulmonary artery). Repositioning of a deployed valve may cause damage to or failure of the TPV and injury to the patient. Refer to section below for a list of potential adverse events associated with the Harmony TPV implantation. Ensure the capsule is closed before DCS removal. If increased resistance is encountered when removing the DCS through the introducer sheath, do not force passage. Increased resistance may indicate a problem and forced passage may result in damage to the device and harm to the patient. If the cause of resistance cannot be determined or corrected, remove the DCS and introducer sheath as a single unit over the guidewire, and inspect the DCS and confirm that it is complete. If there is a risk of coronary artery compression, assess the risk and take the necessary precautions. Endocarditis is a potential adverse event associated with all bioprosthetic valves. Patients should make their health care providers aware that they have a bioprosthetic valve before any procedure. Postprocedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Prophylactic antibiotic therapy is recommended for patients receiving a TPV before undergoing dental procedures. Postprocedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment and/or institutional protocol. Excessive contrast media may cause renal failure. Preprocedure, measure the patient's creatinine level. During the procedure, monitor contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures are associated with the risk of radiation damage to the skin, which may be painful, disfiguring, and long-term.
Potential Adverse Events: Potential risks associated with the implantation of the Harmony TPV may include, but are not limited to, the following: • death • valve dysfunction • tissue deterioration • hematoma • heart failure • cerebrovascular incident • perforation • rupture of the right ventricular outflow tract (RVOT) • compression of the aortic root • compression of the coronary arteries • sepsis • pseudoaneurysm • erosion • stent fracture • arrhythmias • device embolization or migration • pulmonary embolism • occlusion of a pulmonary artery • laceration or rupture of blood vessels • device misorientation or misplacement • valve deterioration • regurgitation through an incompetent valve • physical or chemical implant deterioration • paravalvular leak • valve dysfunction leading to hemodynamic compromise • residual or increasing transvalvular gradients • progressive stenosis and obstruction of the implant • hemorrhage • endocarditis • thromboembolism • thrombosis • thrombus • intrinsic and extrinsic calcification • bleeding • bleeding diathesis due to anticoagulant use • fever • pain at the catheterization site • allergic reaction to contrast agents • infection • progressive pulmonary hypertension • progressive neointimal thickening and peeling • leaflet thickening • hemolysis
General surgical risks applicable to transcatheter pulmonary valve implantation: • abnormal lab values (including electrolyte imbalance and elevated creatinine) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.
Please reference the Harmony TPV system Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.
Caution: Federal Law (USA) restricts these devices to the sale by or on the order of a physician

The Medtronic CardioVascular Coding Hotline is available to respond to your coding questions at 877-347-9662

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