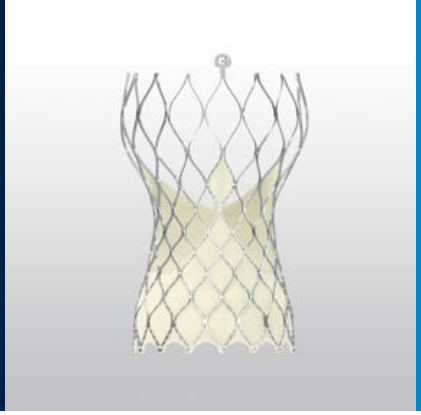
TRANSCATHETER AORTIC VALVE REPLACEMENT 2016 CODING AND REIMBURSEMENT



This information is provided for your consideration. It is the provider's responsibility to determine and submit appropriate codes, modifiers, and charges for the services rendered.

Hospital Coding And Reimbursement

Billing requirements for hospital claims

- Submit the 8 digit registry number preceded by the letters 'CT' on the inpatient paper claim form
- Diagnosis code Z00.6 - Encounter for examination for normal comparison and control in clinical research program
- Bill type 11X – Inpatient, Condition code 30 Qualifying Clinical Trial

Inpatient Procedure Code (ICD-9 to ICD-10 PCS Crosswalk)

ICD-9 CM Procedure Code and Description	ICD- 10 Codes (Implementation date is October 01, 2015)
35.05 Endovascular replacement of aortic valve	02RF38Z Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach

Inpatient Reimbursement

New MS-DRGs Effective October 01, 2014

ITEM AND CODE INSTRUCTION			
MS-DRG	**MS-DRG Descriptions**	**Relative Weight**	**FY2016 Medicare Average Payment[1]**
266	Endovascular Cardiac Valve Replacement w MCC	8.5986	$50,772
267	Endovascular Cardiac Valve Replacement wo MCC	6.5575	$38,720

Hospital Billing Detail

Differences in Hospital Billing Requirements

All TAVR Claims: FDA-Approved Indications and IDE Clinicals Trials

ITEM AND CODE INSTRUCTION	
Diagnosis Code	Z00.6 - Encounter for examination for normal comparison and control in clinical research program
Bill Type	11X - Inpatient
Condition Code	30 - Qualifying Clinical Trial
Procedure Code	35.05 – Endovascular replacement of aortic valve (ICD-10=02RF38Z)

Differences in Submitting Claims for FDA-Approved Indications vs. IDE Clinical Trials

ITEM AND CODE INSTRUCTION			
Form Type	**Form Locator**	**FDA-Approved Indications**	**IDE Clinical Trials (e.g. Medtronic SURTAVI Study)**
Paper Form UB-04 (CMS-1450)	FL39-41 (Value Code)	D4 01737528 (D4 + Registry #)	D4 01586910 (D4 + NCT #)
	FL 42 (Revenue Code) FL 43 (IDE Number)	0278 (rev code) N/A	0624 (rev code) G120169 (IDE #)
Electronic Form 837i	Loop 2300 REF02 (REF01=P4) (Value Code)	01737528 (Registry #)	01586910 (NCT #)
	Segment 2300 REF02(REF01=LX) (IDE Number)	N/A	G120169 (IDE #)

FL: Form Locator **NCT:** National Clinical Trial Number **IDE:** Investigational Device Exemption

Sources: TAVR Claims Processing Instructions: http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf

CMS CHANGE REQUEST 8401: http://www.cms.gov/Regulations-and-Guidance/Transmittlas/Downlaods/R2955CP.pdf

Reimbursement Disclaimer

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[1] Source: Medicare FY2016 Hospital Inpatient Prospective Payment System (IPPS) 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-Regulations.html

INDICATIONS The Medtronic CoreValve and CoreValve Evolut R systems are indicated for use in patients with symptomatic heart disease due to either severe native calcific aortic stenosis or failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, Society of Thoracic Surgeons predicted risk of operative mortality score ≥8% or at a ≥15% risk of mortality at 30 days).

CONTRAINDICATIONS The CoreValve and CoreValve Evolut R systems are contraindicated for patients presenting with any of the following conditions: known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or sensitivity to contrast media, which cannot be adequately premedicated; ongoing sepsis, including active endocarditis; preexisting mechanical heart valve in aortic position.

WARNINGS *General* Implantation of the CoreValve and CoreValve Evolut R systems should be performed only by physicians who have received Medtronic CoreValve training. This procedure should only be performed where emergency aortic valve surgery can be performed promptly. Mechanical failure of the delivery catheter system and/or accessories may result in patient complications. Transcatheter Aortic Valve (Bioprosthesis) Accelerated deterioration of the bioprosthesis may occur in patients presenting with an altered calcium metabolism.

PRECAUTIONS *General* The safety and effectiveness of the CoreValve and CoreValve Evolut R systems have not been evaluated in the pediatric population. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in the following patient populations: patients who do not meet the criteria for symptomatic sever native aortic stenosis as defined: (1) symptomatic severe high gradient aortic stenosis – aortic valve area ≤1.0cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient ≥40 mmHg; or a peak aortic-jet velocity ≥4.0 m/s, (2) symptomatic severe low-flow/low-gradient aortic stenosis – aortic valve area ≤1.0cm^2 or aortic valve area index ≤0.6 cm^2/m^2, a mean aortic valve gradient <40 mmHg; and a peak aortic-jet velocity <4.0 m/s ; who are at moderate or low surgical risk (predicted perioperative mortality risk of <15%); with untreated, clinically significant coronary artery disease requiring revascularization; with a preexisting prosthetic heart valve with a rigid support structure in either the mitral or pulmonic position if either the preexisting prosthetic heart valve could affect the implantation or function of the bioprosthesis or the implantation of the bioprosthesis could affect the function of the preexisting prosthetic heart valve; with cardiogenic shock manifested by low cardiac output, vasopressor dependence, or mechanical hemodynamic support. The safety and effectiveness of a CoreValve or CoreValve Evolut R bioprosthesis implanted within a failed preexisting transcatheter bioprosthesis has not been demonstrated. Implanting a CoreValve or CoreValve Evolut R bioprosthesis in a degenerated surgical bioprosthesis [transcatheter aortic valve in surgical aortic valve (TAV in SAV)] should be avoided in the following conditions. The degenerated surgical bioprosthesis presents with a: significant concomitant perivalvular leak (between the prosthesis and the native annulus), is not securely fixed in the native annulus, or is not structurally intact (eg, wireform frame fracture); partially detached leaflet that in the aortic position may obstruct a coronary ostium; stent frame with a manufacturer's labeled inner diameter <17 mm. The safety and effectiveness of the bioprosthesis for aortic valve replacement have not been evaluated in patient populations presenting with the following: blood dyscrasias as defined: leukopenia (WBC <1000 cells/mm^3), thrombocytopenia (platelet count <50,000 cells/mm^3), history of bleeding diathesis or coagulopathy, or hypercoagulable states; congenital bicuspid or unicuspid valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation [3-4+]); moderate to severe (3-4+) or severe (4+) mitral or severe (4+) tricuspid regurgitation; hypertrophic obstructive cardiomyopathy; new or untreated echocardiographic evidence of intracardiac mass, thrombus, or vegetation; native aortic annulus size <18 mm or >29 mm for CoreValve and <18 mm or >26 mm for CoreValve Evolut R per the baseline diagnostic imaging or surgical bioprosthetic aortic annulus size <17 mm or >29 mm for CoreVavle and <17 mm or >26 mm for CoreValve Evolut R; transarterial access not able to accommodate an 18-Fr sheath or the 14-Fr equivalent EnVeo R InLine sheath; sinus of valsalva anatomy that would prevent adequate coronary perfusion; moderate to severe mitral stenosis; severe ventricular dysfunction with left ventricular ejection fraction (LVEF) <20%;; symptomatic carotid or vertebral artery disease; severe basal septal hypertrophy with an outflow gradient.

Prior to Use Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the vapors. Damage may result from forceful handling of the catheter. Prevent kinking of the catheter when removing it from the packaging.This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. 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.The bioprosthesis size must be appropriate to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. Refer to Instructions for Use for available sizes. Failure to implant a device within the sizing matrix could lead to adverse effects such as those listed below. Patients must present with access vessel diameters of ≥6 mm for the CoreValve system and ≥5 mm for the CoreValve Evolut R system or an ascending aortic (direct aortic) access site ≥60 mm from the basal plane for both systems. Implantation of the bioprosthesis should be avoided in patients with aortic root angulation (angle between plane of aortic valve annulus and horizontal plane/vertebrae) of >30° for right subclavian/axillary access or >70° for femoral and left subclavian/axillary access. Use caution when using the subclavian/axillary approach in patients with a patent LIMA graft or patent RIMA graft. For direct aortic access, ensure the access site and trajectory are free of patent RIMA or a preexisting patent RIMA graft.

During Use For direct aortic and subclavian access procedures, care must be exercised when using the tip-retrieval mechanism to ensure adequate clearance to avoid advancement of the catheter tip through the bioprosthesis leaflets during device closure. For direct aortic access procedures, use a separate introducer sheath; do not use the EnVeo R InLine sheath. Adequate rinsing of the bioprosthesis with sterile saline, as described in the Instructions for Use, is mandatory before implantation. During rinsing, do not touch the leaflets or squeeze the bioprosthesis. If a capsule becomes damaged during loading or the capsule fails to close, replace the entire system (bioprosthesis, catheter, and CLS). Do not use a catheter with a damaged capsule. After a bioprosthesis has been inserted into a patient, do not attempt to reload that bioprosthesis on the same or any other catheter. AccuTrak DCS Only: During implantation, if resistance to deployment is encountered (e.g., the micro knob starts clicking or is tight or stuck), apply upward pressure to the macro slider while turning the micro knob. If the bioprosthesis still does not deploy, remove it from the patient and use another system. AccuTrak DCS Only: Once deployment is initiated, retrieval of the bioprosthesis from the patient (e.g., use of the catheter) is not recommended. Retrieval of a partially deployed valve using the catheter may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. AccuTrak DCS Only: During deployment, the bioprosthesis can be advanced or withdrawn as long as annular contact has not been made. Once annular contact is made, the bioprosthesis cannot be advanced in the retrograde direction; if necessary, and the frame has only been deployed ≤2/3 of its length, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction. EnVeo R DCS Only: If a misload is detected, unsheath the bioprosthesis and examine the bioprosthesis for damage (for example, permanent frame deformation, frayed sutures, or valve damage). Do not attempt to reload a damaged bioprosthesis. Do not load the bioprosthesis onto the catheter more than 2 times or after it has been inserted into a patient. EnVeo R DCS Only: Use the deployment knob to deploy and recapture the bioprosthesis. Do not use the trigger for deploying or recapturing because it could cause inaccurate placement of the bioprosthesis. EnVeo R DCS Only: Once the radiopaque capsule marker band reaches the distal end of the radiopaque paddle attachment (point of no recapture), retrieval of the bioprosthesis from the patient is not recommended. Retrieval after the point of no recapture may cause mechanical failure of the delivery catheter system, aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. EnVeo R DCS Only: During deployment, the bioprosthesis can be advanced or withdrawn as long as annular contact has not been made. Once annular contact is made, the bioprosthesis cannot be advanced in the retrograde direction; recapture until the bioprosthesis is free from annular contact, and then reposition in the retrograde direction. If necessary, and the radiopaque capsule marker band has not yet reached the distal end of the radiopaque paddle attachment, the bioprosthesis can be withdrawn (repositioned) in the antegrade direction. However, use caution when moving the bioprosthesis in the antegrade direction. While the catheter is in the patient, ensure the guidewire is extending from the tip. Do not remove the guidewire from the catheter while the catheter is inserted in the patient. Use the handle of the delivery system to reposition the bioprosthesis. Do not use the outer catheter sheath. Once deployment is complete, repositioning of the bioprosthesis (e.g., use of a snare and/or forceps) is not recommended. Repositioning of a deployed valve may cause aortic root damage, coronary artery damage, myocardial damage, vascular complications, prosthetic valve dysfunction (including device malposition), embolization, stroke, and/or emergent surgery. Do not attempt to retrieve or to recapture (EnVeo DCS only) a bioprosthesis if any one of the outflow struts is protruding from the capsule. If any one of the outflow struts has deployed from the capsule, the bioprosthesis must be released from the catheter before the catheter can be withdrawn. Ensure the capsule is closed before catheter removal. When using a separate introducer sheath, if increased resistance is encountered when removing the catheter 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/or harm to the patient. If the cause of resistance cannot be determined or corrected, remove the catheter and introducer sheath as a single unit over the guidewire, and inspect the catheter and confirm that it is complete. Clinical long-term durability has not been established for the bioprosthesis. Evaluate bioprosthesis performance as needed during patient follow-up. Postprocedure, administer appropriate antibiotic prophylaxis as needed for patients at risk for prosthetic valve infection and endocarditis. Postprocedure, administer anticoagulation and/or antiplatelet therapy per physician/clinical judgment. 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. The safety and efficacy of a CoreValve or CoreValve Evolut R bioprosthesis implanted within the initial transcatheter bioprosthesis have not been demonstrated. However, in the event that a CoreValve or CoreValve Evolut R bioprosthesis must be implanted within the initial transcatheter bioprosthesis to improve valve function, valve size and patient anatomy must be considered before implantation of the bioprosthesis to ensure patient safety (for example, to avoid coronary obstruction). In the event that valve function or sealing is impaired due to excessive calcification or incomplete expansion, a postimplant balloon dilatation of the bioprosthesis may improve valve function and sealing. To ensure patient safety, valve size and patient anatomy must be considered when selecting the size of the balloon used for dilatation. The balloon size chosen for dilatation should not exceed the diameter of the native aortic annulus or, for surgical bioprosthetic valves, the manufacturer's labeled inner diameter. Refer to the specific balloon catheter manufacturer's labeling for proper instruction on the use of balloon catheter devices. Note: Bench testing has only been conducted to confirm compatibility with NuMED Z-MED IITM Balloon Aortic Valvuloplasty catheters where CoreValve or CoreValve Evolut R bioprosthesis device performance was maintained after dilation. Data on File.

POTENTIAL ADVERSE EVENTS Potential risks associated with the implantation of the CoreValve or CoreValve Evolut R transcatheter aortic valve may include, but are not limited to, the following: • death • myocardial infarction, cardiac arrest, cardiogenic shock, cardiac tamponade • coronary occlusion, obstruction, or vessel spasm (including acute coronary closure) • cardiovascular injury (including rupture, perforation, tissue erosion, or dissection of vessels, ascending aorta trauma, ventricle, myocardium, or valvular structures that may require intervention) • emergent surgical or transcatheter intervention (for example, coronary artery bypass, heart valve replacement, valve explant, percutaneous coronary intervention [PCI], balloon valvuloplasty) • prosthetic valve dysfunction (regurgitation or stenosis) due to fracture; bending (out-of-round configuration) of the valve frame; underexpansion of the valve frame; calcification; pannus; leaflet wear, tear, prolapse, or retraction; poor valve coaptation; suture breaks or disruption; leaks; mal-sizing (prosthesis-patient mismatch); malposition (either too high or too low)/malplacement • prosthetic valve migration/embolization • prosthetic valve endocarditis • prosthetic valve thrombosis • delivery catheter system malfunction resulting in the need for additional re-crossing of the aortic valve and prolonged procedural time • delivery catheter system component migration/embolization • stroke (ischemic or hemorrhagic), transient ischemic attack (TIA), or other neurological deficits • heart failure • cardiac failure or low cardiac output • ancillary device embolization • individual organ (for example, cardiac, respiratory, renal [including acute kidney failure]) or multi-organ insufficiency or failure • major or minor bleeding that may require transfusion or intervention (including life-threatening or disabling bleeding) • vascular access-related complications (eg, dissection, perforation, pain, bleeding, hematoma, pseudoaneurysm, irreversible nerve injury, compartment syndrome, arteriovenous fistula, stenosis) • mitral valve regurgitation or injury • conduction system disturbances (for example, atrioventricular node block, left-bundle branch block, asystole), which may require a permanent pacemaker • infection (including septicemia) • hypotension or hypertension • hemolysis • peripheral ischemia • bowel ischemia • abnormal lab values (including electrolyte imbalance) • allergic reaction to antiplatelet agents, contrast medium, or anesthesia • exposure to radiation through fluoroscopy and angiography • permanent disability.

Please reference the CoreValve and CoreValve Evolut R Instructions for Use for more information regarding indications, warnings, precautions and potential adverse events.

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

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