2019 Facility and Physician Billing Guide

Transcatheter Heart Valve Replacement Technologies

Physician Inpatient Coding for TAVR

Facilities and Physicians use Current Procedural Terminology (CPT[1]) codes to bill for procedures and services. Each CPT code is assigned unique relative value units (RVUs), which are used to determine payment by the Centers for Medicare and Medicaid Services (CMS). All the CPT codes used to bill for TAVR procedures are listed below.

CPT Code[1,2]	Description	2019 National Avg. Physician Payment (Final JAN-DEC)	Each Physician Payment (Modifier-62)*	2019 Facility RVUs
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach	$1,423	$889	39.48
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach	$1,553	$971	43.10
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach	$1,609	$1,006	44.64
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach	$1,663	$1,039	46.14
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; trans-aortic approach (e.g., median sternotomy, mediastinotomy)	$1,868	$1,168	51.83
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; trans-apical exposure (e.g., left thoracotomy)	$2,019	$1,262	56.03
Add-on Codes				
33367+	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (list separately in addition to code for primary procedure)	$659	NA	18.29

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CPT Code[1, 2]	Description	2019 National Avg. Physician Payment (Final JAN-DEC)	Each Physician Payment (Modifier-62)*	2019 Facility RVUs
33368+	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (list separately in addition to code for primary procedure)	$783	NA	21.72
33369+	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (list separately in addition to code for primary procedure)	$1,033	NA	28.67

Note: *As per the CMS's NCD for TAVR, TAVR is a two-physician (IC & CS) procedure. Medicare payment for each physician is 62.5% of the established national average payment [8]. +33367,33368 and 33369 are add-on codes which does not require modifier 62 hence each physician payment of 62.5% does not apply.
Note: Medicare will only pay TAVR physician claims with these CPT codes when billed with the Place of Service (POS) code 21 (Inpatient Hospital), modifier 62 (two surgeons/co-surgeons), modifier Q0 (zero) signifying CED participation (qualifying registry or qualified clinical study) and ICD-10 secondary diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) Medicare requires reporting of the Clinical Trial (CT) number on the claim form. For example, the CT number for the TVT Registry is CT01737528. Medicare may return other claims as unprocessable.* Codes 33361-33369 have a 0 day global period; Codes 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368 and 33369 do not include cardiac catheterization [93451-93572] when performed at the time of the procedure for diagnostic purposes prior to aortic valve replacement. Codes 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368 and 33369 include all other catheterization[s], temporary pacing, intraprocedural contrast injection[s], fluoroscopic radiological supervision and interpretation, and imaging guidance, which are not reported separately when performed to complete the aortic valve procedure.

Additional Notes[1]

33361-33369 Transcatheter Aortic Valve Replacement

Includes:

- Access and Implantation of the aortic valve (33361-33366)
- Access sheath placement
- Advancement of valve delivery system
- Arteriotomy closure
- Balloon aortic valvuloplasty
- Cardiac or open arterial approach
- Deployment of valve
- Percutaneous access
- Temporary pacemaker
- Valve repositioning when necessary
- Radiology procedures:
  - Angiography during and after procedure
  - Assessment of access site for closure
  - Documentation of completion of the intervention
  - Guidances for valve placement
  - Supervision and interpretation

Excludes:

- Percutaneous coronary interventional procedures
- Transvascular ventricular support (33967, 33970, 33973, 33975-33976, 33990-33993, 33999)

Code also add-on codes for cardiopulmonary bypass, when appropriate (33367-33369)

Code also cardiac catheterization services for purposes other than TAVR/TAVI

Code also diagnostic coronary angiography at a different session from the interventional procedure

Code also diagnostic coronary angiography at the same time as TAVR/TAVI when:

A previous study is available, but documentation states the patient's condition has changed since the previous study, visualization of the anatomy/pathology is inadequate, or a change occurs during the procedure warranting additional evaluation of an area outside the current target area

No previous catheter-based coronary angiography study is available, and a full diagnostic study is performed, with the decision to perform the intervention based on that study

Code also modifier 59 when diagnostic coronary angiography procedures are performed as separate and distinct procedural services on the same day or session as TAVR/TAVI

Code modifier 62, as well as TAVI/TAVR procedures, require the work of two physicians

Do not report separately when included in the TAVR/TAVI service (93452-93453, 93458-93461, 933567)

Hospital Inpatient Diagnosis and Procedure Coding

Medicare inpatient hospital reimbursement is based upon the Medicare Severity Diagnostic-Related Group (MS-DRG) classification system, which assigns MS-DRGs based on ICD-9-CM diagnosis and procedure codes. The following codes generally describe diagnosis and procedures associated with the use of the Edwards SAPIEN 3 transcatheter heart valve.

ICD-9-CM[3] Diagnosis Code	Description
424.1	Aortic valve disorders

ICD-10-CM Code (effective Oct. 1st, 2015)	Description
I35.0	Nonrheumatic aortic (valve) stenosis

ICD-9-CM[3] Diagnosis Code	Description
35.05	Endovascular replacement of aortic valve
35.06	Transapical replacement of aortic valve

ICD-10-CM Code (effective Oct. 1st, 2015)	Description
02RF38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach
02RF38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach

Pursuant to the final rule for the FY 2015 hospital Inpatient Prospective Payment System (IPPS), CMS created new MS-DRGs for endovascular cardiac valve replacements, effective October 1, 2014.

MS-DRG[5]	Description	FY 2019 Relative Weight	FY 2019 National Average Payment[7]	FY 2019 Geometric Mean-LOS
266	Endovascular Cardiac Valve Replacement with MCC	7.1915	$43,908	4.0
267	Endovascular Cardiac Valve Replacement without MCC	5.8481	$35,706	2.3

Note: Medicare will only pay TAVR facility claims with these ICD-10-CM codes when billed with the ICD-10 secondary diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) and condition code 30 (qualifying clinical trial). Medicare will return all other claims as unprocessable.

Principal Diagnosis for Valve-in-Valve with the Edwards SAPIEN 3 Transcatheter Heart Valve

Depending on the circumstances, there are several ICD-10-CM diagnosis codes that could be used as the principal diagnosis when the encounter is specifically for performing a valve-in-valve procedure at a different operative encounter from the prior surgical valve placement. From a coding perspective, the options are following.

Scenario	ICD-10 Diagnosis Code	ICD-10 Code Description
If the previously placed valve was malpositioned or became displaced	T82.222A	Displacement of biological heart valve graft, initial encounter
If the previously placed valve developed stenosis prematurely	T82.857A	Stenosis of cardiac prosthetic devices, implants and grafts, initial encounter
If the previously placed valve developed regurgitation prematurely	T82.223A	Leakage of biological heart valve graft, initial encounter
If the previously placed valve developed stenosis or regurgitation as an expected occurrence as it degenerates toward valve end-of-life	Z45.09	Encounter for adjustment and management of other cardiac device

Reimbursement Hotline: (303) 524-3854 or edwards@rpihotline.com

Important Safety Information

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System and Accessories

Indications: The Edwards SAPIEN 3 Ultra transcatheter heart valve system and accessories are indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator); and are also indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic or mitral valve who are judged by a Heart Team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the STS risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications: The valve and delivery systems are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets.

Precautions: Safety, effectiveness, and durability have not been established for THV-in-THV procedures. Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+); pre-existing prosthetic ring in any position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the Edwards Axela sheath, such as severe obstructive calcification or severe tortuosity; excessive calcification at access site; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium, or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever. Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; injury to the mitral valve; device explants; mediastinitis; mediastinal bleeding; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

Edwards Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29mm SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

Indications: The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 Ultra transcatheter heart valve and the Edwards SAPIEN 3 transcatheter heart valve for implantation.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. Do not resterilize or reuse the devices. There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: For special considerations associated with the use of the Edwards Crimper prior to THV implantation, refer to the THV Instructions for Use.

Potential Adverse Events: There are no known potential adverse events associated with the Edwards Crimper.

References

1. Current Procedure Terminology (CPT) copyright 2018, American Medical Association (AMA). All rights reserved. CPT is a registered trademark of the AMA. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Applicable FARS/DFARS restrictions apply to government use.
2. Not all codes provided are applicable for the clinical scenarios in which Edwards Lifesciences' Transcatheter Heart Valve technologies are used. The provider is responsible for selecting the most appropriate code(s) for the patient's clinical presentation. When diagnostic services are performed, it may be appropriate to add applicable codes according to the service provided following the correct coding guidelines. Services that are considered a component of another procedure may not always be coded and billed separately.
3. Centers for Medicare & Medicaid Services (CMS). Updates and Revisions to ICD-9-CM Procedure Codes (Addendum). FY 2012 Medicare Addendum, ICD-9-CM Volume 3, Procedures. 26 October 2011. <http://www.cms.gov/icd9providerdiagnosticcodes/04_addendum.asp> and <http://www.cms.gov/ICD9ProviderDiagnosticCodes/Downloads/FY2012_Addenda.pdf>. CMS MLN Matters MM7897, National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR), Revised 25 September, 2012 <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7897.pdf> CMS MLN Matters MM8255, NCD for TAVR- Implementation of Mandatory Reporting of Clinical Trial Number. Revised July, 2013 <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8255.pdf>
4. DRG Expert: A Comprehensive Guidebook to the DRG Classification System, 31st Edition, 2019.
5. Centers for Medicare and Medicaid Services, Physician Fee Schedule Relative Value Files http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files.html. Accessed 2019
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7. Medicare Access and CHIP Authorization Act of 2015- Public Law 114-10-APR. 16,2015.
8. International Classification of Diseases, 10th Revision, Clinical Modification 2017 ICD-10 Expert for hospitals, The complete official code set.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

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