**PHYSICIAN INPATIENT CODING**

Clinicians use Current Procedural Terminology (CPT) Category III codes to track the use of emerging technology, services, and procedures for clinical efficacy, utilization and outcomes, and to facilitate billing. Category III codes are temporary and do not have relative value units (RVUs) assigned to them unlike the “permanent” CPT Category I codes. Payment has not been established and is therefore based on the payers’ policies rather than a yearly fee schedule.

The below procedures have an effective date of January 1, 2013.

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR – endovascular approach</td>
<td>33361*</td>
<td>TAVR with prosthetic valve; percutaneous femoral artery approach</td>
</tr>
<tr>
<td></td>
<td>33362*</td>
<td>TAVR with prosthetic valve; open femoral artery approach</td>
</tr>
<tr>
<td></td>
<td>33367*</td>
<td>TAVR with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (eg, femoral vessels) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td></td>
<td>33368*</td>
<td>TAVR with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td></td>
<td>33369*</td>
<td>TAVR with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (eg, aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>TAVR – transapical approach</td>
<td>0318T*</td>
<td>Implantation of catheter-delivered prosthetic aortic heart valve, open thoracic approach, (eg, transapical, other than transaortic)</td>
</tr>
</tbody>
</table>

**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-9 secondary diagnosis code V70.7 (Examination of participant in clinical trial). Medicare will return all other claims as unprocessable.

*Codes 33361, 33362, 33367, 33368, 33369 and 0318T 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, 33367, 33368, 33369 and 0318T 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.
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 transcatheter heart valve technologies.

<table>
<thead>
<tr>
<th>ICD-9-CM Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>424.1</td>
<td>Aortic valve disorders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9-CM Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.05</td>
<td>Endovascular replacement of aortic valve</td>
</tr>
<tr>
<td>35.06</td>
<td>Transapical replacement of aortic valve</td>
</tr>
</tbody>
</table>

Cardiac Catheterization

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>216</td>
<td>Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC</td>
</tr>
<tr>
<td>217</td>
<td>Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC</td>
</tr>
<tr>
<td>218</td>
<td>Cardiac Valve and Other Major Cardiothoracic Procedures without MCC or CC</td>
</tr>
<tr>
<td>219</td>
<td>Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC</td>
</tr>
<tr>
<td>220</td>
<td>Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC</td>
</tr>
<tr>
<td>221</td>
<td>Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization without MCC or CC</td>
</tr>
</tbody>
</table>

Note: Medicare will only pay TAVR facility claims with these ICD-9-CM codes when billed with the ICD-9 secondary diagnosis code V70.7 (Examination of participant in clinical trial) and condition code 30 (qualifying clinical trial). Medicare will return all other claims as unprocessable.

Reimbursement Hotline: 1-800-471-9387

EDWARDS SAPIEN TRANSCATHETER HEART VALVE AND RETROFLEX 3 DELIVERY SYSTEM

Indications: The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transfemoral delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction >20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to either be: 1) inoperable and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis; or 2) be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons predicted operative risk score >8% or are judged by the heart team to be at a ≥15% risk of mortality for surgical aortic valve replacement.

Indications: The RetroFlex 3 delivery system is indicated for the transfemoral delivery of the Edwards SAPIEN transcatheter heart valve.

Contraindications: The bioprosthesis and delivery system 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 is an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments. Incorrect sizing of the bioprosthesis may lead to paravalvular leak, migration, embolization and/or annular rupture. Accelerated deterioration of the bioprosthesis may occur in patients with an altered calcium metabolism. Bioprostheses must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Bioprosthetic leaflets mishandled or damaged during any part of the procedure will require replacement of the bioprosthesis. Caution should be exercised in implanting a bioprosthesis in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve devices should be carefully assessed prior to implantation of the bioprosthesis to ensure proper bioprosthesis positioning and deployment. Patients presenting with combination AV low flow, low gradient should undergo additional evaluation to establish the degree of aortic stenosis. Use of excessive contrast media usage 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 chromium, nickel, molybdenum, manganese, copper, 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.

Precautions: Long-term durability has not been established for the bioprosthesis. Regular medical follow-up is advised to evaluate bioprosthesis performance. 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. Bioprosthetic valve recipients should be maintained on anticoagulant and antiplatelet therapy (e.g. clopidogrel or ticlopidine [75 mg/day]) for 6 months post-procedure and aspirin (75-100 mg/day) for life, except when contraindicated, as determined by their physician. The safety of the bioprosthesis implantation has not been established in patients who have: pre-existing prosthetic heart valve or valve repair device in any position; severe ventricular dysfunction with ejection fraction of <20%; and hypertrophic cardiomyopathy with or without obstruction (HOCM). Safety and effectiveness have not been established for patients who are candidates for surgical aortic valve replacement. Safety, effectiveness, and durability have not been established for valve-in-valve procedures. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; congenital unicuspid or congenital bicuspid aortic valve; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation >3+); pre-existing prosthetic heart valve or prosthetic ring in any position; severe mitral annular calcification (MAC), severe (≥3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as: leukopenia (WBC <3000 mm3), acute anemia (Hb <9 g/dL), thrombocytopenia (platelet count <50,000 cells/mm3), 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; native aortic annulus size <18 mm or >25 mm as measured by echocardiogram; Patient has been offered surgery but has refused surgery; 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

![Transfemoral Aortic Valve Replacement](Image)
EDWARDS TRANSFEMORAL BALLOON CATHETER

Indications: The Edwards Transfemoral balloon catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN transcatheter heart valve.

Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient’s medical condition could affect successful use of this catheter.

Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis Instructions for Use. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum.

Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet insufficiency, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, vascular or perivascular events, and infection. Reference the Edwards SAPIEN Transcatheter Heart Valve with the Retroflex 3 Delivery System Instructions for Use for a full list of potential adverse events.

EDWARDS SAPIEN TRANSCATHETER HEART VALVE WITH THE ASCENDRA BALLOON CATHETER

Indications: The Edwards SAPIEN transcatheter heart valve, model 9000TFX, sizes 23 mm and 26 mm, is indicated for transapical delivery in patients with severe symptomatic calcified native aortic valve stenosis without severe aortic insufficiency and with ejection fraction >20% who have been examined by a heart team including an experienced cardiac surgeon and a cardiologist and found to be operative candidates for aortic valve replacement but who have a Society of Thoracic Surgeons operative risk score >3% or are judged by the heart team to be at >15% risk of mortality for surgical aortic valve replacement.

Contraindications: The bioprosthesis and delivery system 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 is an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments. Incorrect sizing of the bioprosthesis may lead to paravalvular leak, migration, embolization, valve leaflet injury, and vascular rupture. Accelerated deterioration of the bioprosthesis may occur in patients with an altered calcium metabolism. Bioprosthesis must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Bioprosthesis leaflets mishandled or damaged during any part of the procedure will require replacement of the bioprosthesis. Caution should be exercised in implanting a bioprosthesis in patients with clinically significant coronary artery disease. Patients with pre-existing mitral valve devices should be carefully assessed prior to implantation of the bioprosthesis with any prior mitral valve surgery. All low flow situations, low output, hypovolemia, or pre-existing heart failure may require additional evaluation to establish the degree of aortic stenosis. 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 chromium, nickel, molybdenum, manganese, copper, 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. The safety and efficacy of the transcatheter procedure has only been evaluated in those patient populations where the transfemoral procedure delivery is not suitable.

Precautions: Long-term durability has not been established for the bioprosthesis. Regular medical follow-up is advised to evaluate bioprosthesis performance. 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. Bioprosthetic valve recipients should be maintained on anticoagulant and antiplatelet therapy (e.g. clopidogrel or ticlopidine [75 mg/day]) for 6 months post-procedure and aspirin (75-100 mg/day) for life, except when contraindicated, as determined by their physician. The safety of the bioprosthesis implantation in these patients has not been established in patients who have: pre-existing prosthetic heart valve or valve repair device in any position; severe ventricular dysfunction with ejection fraction <20%; and hypertrophic cardiomyopathy with or without obstruction (HOCM). Safety and effectiveness have not been established for patients who are candidates for surgical aortic valve replacement. Safety, effectiveness, and durability have not been established for valve-in-valve procedures. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; congenital unicusp or congenital bicuspid aortic valve; mixed aortic stenosis and aortic regurgitation with predominant aortic regurgitation; prosthetic valve and endocarditis; severe annular calcification; severe mitral annular calcification (MAC), severe (>3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as: leukopenia (WBC <3000 mm3), acute anemia (Hb <9 g/dL), thrombocytopenia (platelet count <50,000 cells/mm3), 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 prereduced; native aortic annulus size <18 mm or >25 mm as measured by echocardiogram; patient has been offered surgery but has refused surgery; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximum 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; and bulky calcified aortic valve leaflets in close proximity to coronary ostia.

Potential Adverse Events: Potential risks associated with the overall procedure including potential access complications associated with standard cardiac catheterization for the transfemoral access procedure, 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; paraplegia; permanent disability; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; infundibulum injury; cardiovascular injury including perforation or dissection of vessels, ventricle, myocardium or valvular structures that may require intervention; annular tear or rupture; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material or thrombus; thrombus formation, plaque dislodgment, and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion, and/or death; infection including sepsisemia and endocarditis; heart failure; myocardial infarction; valve leaflet insufficiency or failure; aortic regurgitation; paravalvular or transvalvular leak; valve regurgitation; hemothysis; device explants; nonstructural dysfunction; and non-emergent reoperation. All listed risks may include symptoms associated with the above mentioned medical conditions.
arrhythmia; retroperitoneal bleed; femoral AV fistula or pseudoaneurysm; reoperation; peripheral ischemia or nerve injury; restenosis; pulmonary edema; pleural effusion; bleeding; balloon rupture; balloon separation following balloon rupture; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia or to contrast media; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; fever; mechanical failure of delivery system and/or accessories; suturing of peripheral coronary artery; and valvular tearing or trauma. Additional potential risks specifically associated with the use of the bioprosthesis include, but may not be limited to the following: 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; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflets retraction, stent creep, suture line disruption of components of a prosthetic valve, thickening, stenosis, or other); device degenera-
tion; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; and non-emergent reoperation. All listed risks may include symptoms associated with the above mentioned medical conditions.

ASCENDRA BALLOON AORTIC VALVULOPLASTY CATHETER

Indications: The Ascendra Balloon Aortic Valvuloplasty Catheter is indicated for valvuloplasty of a stenotic aortic valve prior to implantation of the Edwards SAPIEN transcatheter heart valve.

Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for valvuloplasty. The patient's medical condition could affect successful use of this catheter.

Precautions: For special considerations associated with the use of this device prior to transcatheter heart valve implantation, refer to the bioprosthesis instructions for use (IFU). This catheter has not been tested with any transcatheter valve other than the Edwards SAPIEN transcatheter heart valve. Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. The device is not intended for post-dilatation of deployed transcatheter heart valves. While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum.

Potential Adverse Events: Complications associated with standard catheterization, balloon valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, thrombus formation, plaque dislodgement and embolization that may result in myocardial infarction, stroke, distal peripheral occlusion and/or death, arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valve leaflet dehiscence, severe valve insufficiency, valve restenosis, valve damage, balloon rupture, balloon separation following balloon rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN Transcatheter Heart Valve with the Ascendra Balloon Catheter Instructions for Use for a full list of potential adverse events.

ASCENDRA INTRODUCER SHEATH SET

Indications: The Ascendra Introducer Sheath Set it indicated for the introduction and removal of devices used with the Edwards SAPIEN Transcatheter Heart Valve.

Contraindications: No known contraindications.

Warnings: The Ascendra Introducer Sheath Set must be used with a 0.035” guidewire. Should not be used in patients with apical left ventricular aneurysm.

Precautions: No known precautions.

Potential Adverse Events: Complications associated with cardiac surgical intervention and use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including myocardial injury, thrombus formation, and plaque dislodgement which may result in myocardial infarction, arrhythmia, stroke, and/or death. Reference the Edwards SAPIEN Transcatheter Heart Valve with the Ascendra Balloon Catheter Instructions for Use for a full list of potential adverse events.

Disclaimer

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ment, coding or legal advice. Any and all references to reimbursement codes are provided as examples only and are not intended to be a recommendation or advice as to the appropriate code for the a particular patient, diagnosis, product or procedure or a guarantee or promise of coverage or payment, nor does Edwards Lifesciences warranty that codes listed are appropriate in all related clinical scenarios. It is the responsibility of the provider to determine if coverage exists and what requirements are necessary for submitting a proper claim for reimbursement to a health plan or payer, including the appropriate code(s) for products provided or services rendered. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently; service providers are responsible for all decisions relating to coding and reimbursement matters. Accordingly, Edwards strongly recom-
mends consultation with payers, reimbursement specialists and/or legal counsel regarding appropriate product or procedure codes, coverage, and reimbursement matters.

Reference

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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.


CAUTION: Federal (United States) law restricts the Edwards SAPIEN transcatheter heart valve to sale by or on the order of a physician. This device has been approved by the FDA for specific indications for use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

CAUTION: Federal (United States) law restricts the RetroFlex 3 delivery system, RetroFlex 3 introducer sheath set, RetroFlex dilator kit, RetroFlex balloon catheter, Edwards transfemoral balloon catheter, Ascendra balloon catheter, Ascendra introducer sheath set, Ascendra balloon aortic valvuloplasty catheter, crimpler and Atrion inflation device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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