## 2014 FACILITY AND PHYSICIAN BILLING GUIDE

### TRANSCATHETER AORTIC VALVE REPLACEMENT

This guide is intended to support diagnostic and procedural coding for Transcatheter Aortic Valve Replacement (TAVR) procedures.

**PHYSICIAN INPATIENT CODING**

Facilities and Physicians use Current Procedural Terminology (CPT®) 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.

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>CPT Code1, 2</th>
<th>Description</th>
<th>2014 National Avg. Physician Payment</th>
<th>Each Physician Payment (Modifier-62)*</th>
<th>2014 Facility RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR</td>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
<td>$1,403</td>
<td>$877</td>
<td>39.18</td>
</tr>
<tr>
<td></td>
<td>33362</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
<td>$1,535</td>
<td>$959</td>
<td>42.85</td>
</tr>
<tr>
<td></td>
<td>33363</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
<td>$1,588</td>
<td>$993</td>
<td>44.35</td>
</tr>
<tr>
<td></td>
<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
<td>$1,671</td>
<td>$1,044</td>
<td>46.66</td>
</tr>
<tr>
<td></td>
<td>33365</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)</td>
<td>$1,843</td>
<td>$1,152</td>
<td>51.46</td>
</tr>
<tr>
<td></td>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (eg, left thoracotomy)</td>
<td>$1,994</td>
<td>$1,246</td>
<td>55.69</td>
</tr>
</tbody>
</table>

**Add-on Codes**

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>33367*</td>
<td>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)</td>
<td>$643</td>
<td>NA</td>
<td>17.97</td>
</tr>
<tr>
<td>33368*</td>
<td>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)</td>
<td>$780</td>
<td>NA</td>
<td>21.78</td>
</tr>
<tr>
<td>33369*</td>
<td>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)</td>
<td>$1,029</td>
<td>NA</td>
<td>28.74</td>
</tr>
</tbody>
</table>

**Note:**

1. 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.
2. Medicare 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 requires reporting of the Clinical Trial (CT) number on the claim form. For example, the CT number for the TVT Registry is CT01737528 and the PARTNER II Trial is CT01314313. 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, intra-procedural 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 XT transcatheter heart valve.

<table>
<thead>
<tr>
<th>ICD-9-CM&lt;sup&gt;3&lt;/sup&gt; 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&lt;sup&gt;3&lt;/sup&gt; Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.05&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Endovascular replacement of aortic valve</td>
</tr>
<tr>
<td>35.06&lt;sup&gt;4&lt;/sup&gt;</td>
<td>Transapical replacement of aortic valve</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>MS-DRG&lt;sup&gt;5&lt;/sup&gt;</th>
<th>Description</th>
<th>FY 2015 Relative Weight</th>
<th>FY 2015 National Average Payment&lt;sup&gt;7&lt;/sup&gt;</th>
<th>FY 2015 Geometric Mean-LOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>266</td>
<td>Endovascular Cardiac Valve Replacement with MCC</td>
<td>8.9920</td>
<td>$52,742</td>
<td>8.4</td>
</tr>
<tr>
<td>267</td>
<td>Endovascular Cardiac Valve Replacement without MCC</td>
<td>6.7517</td>
<td>$39,602</td>
<td>5.0</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.

Additional Notes
Diagnostic left heart catheterization codes (93452, 93453, 93458-93461) and the supravalvular aortography code (93567) should not be used with TAVR/TAVI services (33361-33366) to report:
1. Contrast injections, angiography, roadmapping, and/or fluoroscopic guidelines for the TAVR/TAVI,
2. Aorta/left ventricular outflow tract measurement for the TAVR/TAVI, or
3. Post-TAVR/TAVI aortic or left ventricular angiography, as this work is captured in the TAVR/TAVI services codes (33361-33366).

Diagnostic coronary angiography performed at the time of TAVR/TAVI may be separately reportable if:
1. No prior catheter-based coronary angiography study is available and a full diagnostic study is performed, or
2. A prior study is available, but as documented in the medical record:
   a. The patient’s condition with respect to the clinical indication has changed since the prior study, or
   b. There is inadequate visualization of the anatomy and/or pathology, or
   c. There is a clinical change during the procedure that requires new evaluation.
   d. For same session/same day diagnostic coronary angiography services, report the appropriate diagnostic cardiac catheterization codes(s) appended with modifier 59 indicating separate and distinct procedural service from TAVR/TAVI

Diagnostic coronary angiography performed at separate session from an interventional procedure may be separately reportable.

Other cardiac catheterization services are reported separately when performed for diagnostic purposes not intrinsic to TAVR/TAVI.

Percutaneous coronary interventional procedures are reported separately, when performed.
Reimbursement Hotline: 1-800-471-9387

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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.
7. CMS Federal Register, Volume 79; Number 163, August 22, 2014/Rules and Regulations. The FY2015 Final Average standardized amount is $5865.48
8. CMS Federal Register, Volume 77; Number 222, November 16, 2012/Rules and Regulations

CAUTION: Federal (United States) law restricts these devices 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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EDWARDS SAFEN XT TRANSCATHETER HEART VALVE WITH THE NOVAFLEX+ DELIVERY SYSTEM

Indications: The Edwards SAFEN XT Transcatheter Heart Valve, model 0002T0X, is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe aortic valve disease (ASA CI ≥ 0.6 cm²/m²), severe aortic valve gradient of ≥ 40 mmHg, or a peak aortic jet velocity of ≥ 4.0 m/s, and with native anatomy appropriate for the 25, 26, or 28 mm valve system, who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (≥1). The device is not intended for post-dilation of deployed transcatheter heart valves. In those with existing mitral valve devices should be carefully assessed prior to implantation of the THV.

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

Warnings: Do not re-use or re-sterilize the device. The device is designed, intended, and distributed for single use only.

Precautions: This product is contraindicated for tortuous or calcified vessels that would prevent safe entry of the introducer and sheath. Other than standard risks associated with insertion of a cardiovascular device and use of angiography: death; stroke/transient ischemic attack, clusters or neurological embolization; rupture, valvular tearing or trauma, thromboembolic events, and infection. Reference the Edwards SAPIEN XT Transcatheter Heart Valve with the NovaFlex+ Delivery System Instructions for Use for a full list of potential adverse events.

EDWARDS EXPANDABLE INTRODUCTORY SHEAT SET

Indications: The Edwards expandable introducer sheath is intended for the introduction and deployment of the Edwards SAPIEN XT Transcatheter Heart Valve.

Contraindications: This product is contraindicated for tortuous or calcified vessels that would prevent safe entry of the introducer and sheath. Other than standard risks associated with insertion of a cardiovascular device.

Precautions: Do not use the introducer sheath set if the packaging seal is broken or any component is not sterile, have been opened or are damaged (e.g., wrinkled, or stretched), or the expiration date has elapsed.

Adverse Events:
- Potential risks associated with the overall procedure including death, stroke, access site complications, and thromboembolic events.
- Other than standard risks associated with insertion of a cardiovascular device.

EDWARDS BALLOON CATHETER 9300WBC and 9300WBC1

Indications: The Edwards balloon catheter is indicated for vaivuloplasty of a stenotic aortic valve using the Edwards SAPIEN and SAFEN XT transcatheter heart valve.

Contraindications: Other than standard risks associated with insertion of a cardiovascular catheter, there are no known contraindications for catheter implantation.

Warnings: Do not re-use or re-sterilize the device. The balloon is designed, intended, and distributed for single use only.
Molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure
is contraindicated if the tamper evident seal is broken, the storage
system is damaged, or the expiration date has elapsed. Do not mishandle the Ascendra+
Delivering System Instructions for Use for a full list of potential adverse events.

Warnings: The device is designed, intended, and distributed for single use only. Do not
resterilize or reuse the device. The device can be used to support the stability, nonporosity, and
corrosion resistance of the device after reprocessing. Do not resterilize or reuse the device.

Contraindications: Other than standard risks associated with insertion of a cardiovascular
device, this device has not been tested for use without
the Edwards SAPIEN XT Transcatheter Heart Valve for implantation.

As endocarditis or other active infections.

Contraindications: The THV and delivery systems are contraindicated in patients who
are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for
this catheter. This catheter has not been tested with any transcatheter valve other than the Edwards
SAPIEN XT Transcatheter Heart Valve.

Potential Adverse Events: Complications associated with standard catheterization,
balloon angioplasty, or stent implantation can occur.

Contraindications: The THV and delivery systems are contraindicated in patients who
have active bacterial endocarditis or other active infections.

Contraindications: No known contraindications.

CAUTION: Federal (United States) law restricts these devices 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.

No known potential adverse events.