Hospital Coding and Reimbursement

Billing requirements for hospital claims

- Submit the eight-digit registry number preceded by the letter and number “D4” on the inpatient paper claim form (Form Locator 39 - 41)
- 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

ICD-10 PCS PROCEDURE CODE

02RF38Z
Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach

Inpatient Reimbursement

MS-DRGs

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>MS-DRG Descriptions</th>
<th>Relative Weight</th>
<th>FY2019 Medicare Average Payment</th>
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</thead>
<tbody>
<tr>
<td>266</td>
<td>Endovascular Cardiac Valve Replacement w MCC</td>
<td>7.1915</td>
<td>$43,935</td>
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<tr>
<td>267</td>
<td>Endovascular Cardiac Valve Replacement wo MCC</td>
<td>5.8481</td>
<td>$35,727</td>
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</tbody>
</table>

Hospital Billing Detail

Differences in hospital billing requirements

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

<table>
<thead>
<tr>
<th>ITEM AND CODE DESCRIPTION²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis Code</td>
</tr>
<tr>
<td>Bill Type</td>
</tr>
<tr>
<td>Condition Code</td>
</tr>
<tr>
<td>Procedure Code</td>
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### Differences between Submitting Claims for FDA-approved Indications and IDE Clinical Trials

<table>
<thead>
<tr>
<th>Form Type</th>
<th>Form Locator</th>
<th>FDA-approved Indications</th>
<th>IDE Clinical Trials (Information is for illustration only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper Form UB-04</td>
<td>FL39-41 (Value Code)</td>
<td>D4 01737528 (D4 + Registry #)</td>
<td>D4 9999999999 (D4 + NCT #)</td>
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<tr>
<td>(CMS-1450)</td>
<td>FL 42 (Revenue Code) FL 43 (IDE Number)</td>
<td>0278 (rev code) N/A</td>
<td>0624 (rev code) G999999 (IDE #)</td>
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<tr>
<td>Electronic Form 837i</td>
<td>Loop 2300 REF02 (REF01=P4) (Value Code)</td>
<td>01737528 (Registry #)</td>
<td>9999999999 (NCT #)</td>
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<td>Segment 2300 REF02(REF01=LX) (IDE Number)</td>
<td>N/A</td>
<td>G9999999 (IDE #)</td>
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</tbody>
</table>

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

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**Reimbursement Disclaimer**

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules and regulations.

The provider has the responsibility to determine medical necessity and to submit appropriate 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.

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.

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The safety and effectiveness of aortic valve bioprostheses has 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 severe native aortic stenosis; do not have a mean aortic valve gradient ≥ 40 mm Hg; and/or aortic valve area ≤ 0.6 cm²/m², mean aortic valve gradient ≥ 40 mm Hg, and peak aortic-jet velocity ≥ 4.0 m/s. Additionally, for surgical bioprostheses, the manufacturer’s labeled inner diameter. Refer to the specific balloon catheter manufacturer’s labeling for proper sizing.

Use of the EnVeO R InLine sheath does not guarantee successful valve deployment. When using the EnVeO R InLine sheath, the post valve deployment resistances should be investigated to ensure safety. Successful valve deployment does not ensure optimal valve position or function. Potential complications caused by the use of the EnVeO R InLine sheath are similar to those encountered with any other sheath system and/or accessories may result in patient complications. Accelerated deterioration of the bioprosthesis may occur in patients presenting with an altered calcium metabolism.

Use of the EnVeO R InLine sheath and accessories does not preclude the use of additional re-crossing of the aortic valve and prolonged procedural time (for example, coronary artery bypass, percutaneous coronary intervention [PCI], balloon valvuloplasty]. However, removal of the sheath in this situation may result in adverse effects such as those listed below. Patients must be monitored for hemodynamic instability, including hypotension or hypertension, conduction system disturbances (for example, atrioventricular node block, left- or right bundle branch block, third-degree AV block), and/or emergent surgery. Do not attempt to retrieve or to recapture a bioprosthesis if any one of the outflow struts is visible. If any of the outflow struts has been deployed into the aortic valve, the prosthesis must be released from the catheter before the catheter can be withdrawn. Ensure the capsule is closed before catheter withdrawal. When using the EnVeO R InLine sheath, the manufacturer’s labeled inner diameter. Refer to the specific balloon catheter manufacturer’s labeling for proper sizing.

Do not attempt to retrieve or to recapture a bioprosthesis if any one of the outflow struts is visible. If any of the outflow struts has been deployed into the aortic valve, the prosthesis must be released from the catheter before the catheter can be withdrawn. Ensure the capsule is closed before catheter withdrawal. When using the EnVeO R InLine sheath, the manufacturer’s labeled inner diameter. Refer to the specific balloon catheter manufacturer’s labeling for proper sizing.

When using any sheath system, including the EnVeO R InLine sheath, the post valve deployment resistances should be investigated to ensure safety. Successful valve deployment does not ensure optimal valve position or function. Potential complications caused by the use of the EnVeO R InLine sheath are similar to those encountered with any other sheath system and/or accessories may result in patient complications. Accelerated deterioration of the bioprosthesis may occur in patients presenting with an altered calcium metabolism.

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