Center for Medicare and Medicaid Services EVAR Reimbursement: Frequently Asked Questions — PHYSICIANS AND HOSPITAL ADMINISTRATORS

Q: What is this announcement about?
A: The Centers for Medicare and Medicaid Services (CMS) has issued a new Medicare Severity Diagnosis-Related Group (MS-DRG) classification that will result in an increase in the hospital reimbursement for endovascular abdominal aneurysm repair (EVAR) procedures.

Q: When will this new payment regulation go into effect?
A: October 1, 2015

Q: What types of procedures are covered?
A: The new MS-DRG classification applies to minimally invasive catheter-based interventions used for the repair of abdominal aortic aneurysms (AAA) along with 12 other aortic and cardiac procedures.

Q: Besides the repair of AAA, what other aortic and cardiac procedures are covered?
A: The full listing of procedures impacted by the new MS-DRG classification include:

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>Procedure Description</th>
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</thead>
<tbody>
<tr>
<td>37.41</td>
<td>Implantation of prosthetic cardiac support device around the heart</td>
</tr>
<tr>
<td>37.55</td>
<td>Removal of internal biventricular heart replacement system</td>
</tr>
<tr>
<td>37.64</td>
<td>Removal of external heart assist system(s) or device(s)</td>
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<tr>
<td>38.04</td>
<td>Incision of vessel, aorta</td>
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<td>38.14</td>
<td>Endarterectomy, aorta</td>
</tr>
<tr>
<td>38.34</td>
<td>Resection of vessel with anastomosis, aorta</td>
</tr>
<tr>
<td>38.44</td>
<td>Resection of vessel with replacement, aorta, abdominal</td>
</tr>
<tr>
<td>38.64</td>
<td>Other excision of vessels, aorta, abdominal</td>
</tr>
<tr>
<td>38.84</td>
<td>Other surgical occlusion of vessels, aorta, abdominal</td>
</tr>
<tr>
<td>39.24</td>
<td>Aorta-renal bypass</td>
</tr>
<tr>
<td>39.54</td>
<td>Re-entry operation, aorta</td>
</tr>
<tr>
<td>39.71</td>
<td>Endovascular implantation of other graft in abdominal aorta</td>
</tr>
<tr>
<td>39.78</td>
<td>Endovascular implantation of branching or fenestrated graft(s) in aorta</td>
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</tbody>
</table>

Q: What Gore products are used in EVAR procedures?
A: The family of GORE® EXCLUDER® AAA Endoprosthesis products are used in EVAR procedures, a minimally invasive alternative to open surgical repair.
Q: What are the new reimbursement base rates?
A: Cases without Major Complications or Comorbidities (MCC) will see an approximate 14 percent increase in payment. Cases with MCC will receive an approximate 24 percent increase in payment.

Q: What constitutes MCC versus non-MCC cases under this classification?
A: The distinction between cases with or without MCC remains unchanged from the prior DRG classification (DRG 237, 238). Medicare will publish a current list of diagnoses constituting MCC conditions in Table 6i of final rule IPPS 1632 on the Medicare website. A copy of the final rule MCC and CC links will be provided on the coding guidance website once that information becomes available in October.

Q: How will this change impact the reimbursement level for these procedures at my institution?
A: The specific reimbursement rate will differ for each hospital, based on a number of hospital specific variables. In general, a hospital should see the base reimbursement for EVAR cases increase by approximately 14 percent in cases without MCC (DRG 269) and approximately 24 percent in cases with MCC (DRG 268). Your Gore Field Sales Associate can put you in contact with a Health Economics Associate who may assist you with questions related to your facility’s specific situation.

Q: How can my hospital take advantage of the increased benefit?
A: The revised payments will be automatic and seamless. Starting October 1, 2015, when billing to Medicare for EVAR procedures, Medicare’s electronic payment system will automatically process claims at the new reimbursement base rate.

Q: Why did Medicare decide to make this change?
A: Around the time EVAR was first becoming broadly used in the US, a study published in the February 2000 issue of the Journal of Vascular Surgery reported that the average hospital cost of EVAR was roughly $20,000 and the mean reimbursement rate was approximately $19,000. Over the last 15 years, however, the complexity of disease treated with EVAR versus open surgery has increased, leading to higher costs associated with EVAR. Meanwhile, reimbursement rates over this period of time remained relatively flat. With the cost data analysis for EVAR and open surgical repair procedures provided by Gore and others committed to the advancement of EVAR, Medicare agreed that it was necessary to make a change to better align cost and payment for the benefit of patients, hospitals, and physicians.

Q: What role did Gore play in this decision?
A: Gore routinely monitors how reimbursement rates are keeping pace with hospital costs as therapies evolve and gain in popularity. After conducting a cost data analysis of EVAR and other procedures in DRG 237 and 238, Gore, with the support of other parties promoting fair reimbursement for EVAR, submitted a proposal to CMS to reclassify the MS-DRGs associated with EVAR and open surgical repair of AAA to a payment category that better reflected the costs associated with these therapies.
Q: Has a decision like this occurred before?
A: Gore has an established history of proactively monitoring whether reimbursement rates are keeping up with hospital costs as endovascular procedures evolve to include more complex cases. For example, on October 1, 2011, Medicare implemented a proposal made by Gore to reclassify the MS-DRG codes associated with the endovascular implantation of stent-grafts for the treatment of thoracic aortic disease. Like the present decision, this reclassification helped ensure patients, physicians, and hospitals maintained access to the latest technology for the treatment of aortic disease.

Q: Will all hospitals receive the same percentage increase in payment?
A: The new ruling provides that all hospitals receive an increase in their base reimbursement rate of approximately 14 percent for EVAR cases without MCCs and 24 percent for cases with MCCs. The actual change in reimbursement experienced on October 1 may vary from hospital to hospital; however, annual adjustments influencing CMS payments to specific institutions will also go into effect on that date. These factors (examples of which include their wage index, quality incentive adjustments, etc.) are not specific to the DRGs for EVAR, but would be applied generally to the institution following CMS' annual review. As needed, our Health Economics Associates may assist in providing the actual dollar impact to a specific institutions' reimbursement level once the new institutional discount rates are published in October.

Q: A transition to ICD-10 is expected in the future. Will these new reimbursement rates still apply?
A: This ruling anticipates the upcoming transition to ICD-10. As that change is implemented, the ICD-10 coding used for EVAR will be recognized as eligible for the new DRG payment. Additional details will be provided to assist our customers through the transition from ICD-9 to ICD-10 as we approach the implementation date.

Q: Will physicians receive an increase in their payments for EVAR as a result of this change?
A: No. The new payment structure will impact the reimbursement received by institutions, not physicians.

Q: Did other manufacturers contribute to this effort?
A: The increase in the reimbursement rate for EVAR resulted from activities and analyses that were initiated and driven by Gore. As a courtesy, we informed other manufacturers of our efforts and they did not object to our proposed approach.

Q: Will open surgical AAA repair see an increase in payment under this new policy?
A: Yes. Open surgical repair is also classified into DRG 268 / 269.
Q: What is AAA?
A: An abdominal aortic aneurysm — or AAA — is a bulge or ballooning of the abdominal aorta, the artery that carries blood away from the heart to the lower part of the body. Over time, the bulge (known as an aneurysm) can become weak and the force of normal blood pressure can cause the aorta to rupture. This can lead to severe pain, massive internal bleeding, or even sudden death. Most patients with a ruptured aneurysm do not survive emergency treatment, making AAA the third leading cause of sudden death in men over 60.

Q: How is AAA treated?
A: When found early, AAA can be effectively managed in order to keep the aneurysm from bursting or rupturing. A vascular specialist will determine the best course of treatment depending on the size and shape of the aneurysm and other medical conditions. One of the following may be recommended:

- "Watchful waiting." If the aneurysm is small, a doctor may decide to wait and watch carefully to see if there are any changes. Patients are monitored every 6 – 12 months for changes in size of the aneurysm. In addition, a doctor may suggest lifestyle changes such as quitting smoking, lowering blood pressure, modifying diet, or increasing daily exercise.

- Endovascular repair (EVAR). This is a less-invasive alternative to surgical repair, because the procedure occurs without a surgical opening of the aorta. Instead, the surgeon places a synthetic fabric tube (graft) supported by a metal scaffold (stent) inside the aneurysm. Because endovascular aneurysm repair is less invasive than open surgery, hospital stays can be shorter — typically lasting two to four days.

- Open surgical repair. Through an abdominal incision, a surgeon replaces the section of the aorta where the aneurysm has formed with a synthetic fabric tube, or "graft." Open surgical repair is performed under general anesthesia, usually taking three to four hours and may require a hospital stay of seven to ten days.