Endovascular Stent Grafts for Abdominal Aortic Aneurysms

**Description**
Endovascular stent grafts can be used as minimally invasive alternatives to open surgical repair for treatment of abdominal aortic aneurysms (AAAs). Open surgical repair of AAAs has high morbidity and mortality, and endovascular grafts have the potential to reduce the operative risk associated with AAA repair.

**OBJECTIVE**
The objective of this evidence review is to determine whether the use of endovascular aneurysm repair improves the net health outcome in individuals with abdominal aortic aneurysms, ruptured aneurysms, or abdominal aortic aneurysms ineligible for open repair.

**POLICY STATEMENT**
The use of endoprostheses approved by the U.S. Food and Drug Administration as a treatment of abdominal aortic aneurysms (AAAs) may be considered **medically necessary** in any of the following clinical situations:

- an aneurysmal diameter greater than 5.0 cm
- an aneurysmal diameter of 4 to 5.0 cm that has increased in size by 0.5 cm in the last 6 months
- an aneurysmal diameter that measures twice the size of the normal infrarenal aorta
- a ruptured AAA (see Policy Guidelines section).

The use of endoprostheses approved by the Food and Drug Administration as a treatment of AAAs is considered **not medically necessary** when the above criteria are not met, including but not limited to the following clinical situations:

- Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery
- Treatment of aneurysms that do meet the recommended threshold for surgery in patients who are ineligible for open repair due to physical limitations or other factors.

**POLICY GUIDELINES**
For treatment of ruptured abdominal aortic aneurysms with endoprostheses, several factors must be considered including the following:

- The patient must be sufficiently stable to undergo detailed computed tomography examination for anatomic measurements,
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- The aneurysm should be anatomically appropriate for endovascular repair, and
- Specialized personnel should be available.

To monitor for leaking of the graft after implantation, patients will typically undergo routine imaging with computed tomography or ultrasonography every 6 to 12 months, or more frequently if perivascular leaks or aneurysm enlargement are detected.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

A large number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for treatment of AAAs (see Table 1). The original PMA dates are shown. Most stents have undergone device modification, name changes, and have approved supplements to the original PMA. FDA product code MIH.

**Table 1. Abdominal Aortic Stent Grafts Approved by FDA**

<table>
<thead>
<tr>
<th>Stent Name</th>
<th>PMA Applicant</th>
<th>Approved</th>
<th>PMA No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>AneuRx® Prothesis System (AneuRx AAAdvantage Stent Graft)</td>
<td>Medtronic Vascular</td>
<td>1999</td>
<td>P990020</td>
</tr>
<tr>
<td>Ancure® Aortoiliac System</td>
<td>Guidant Endovascular Technologies</td>
<td>2002</td>
<td>P990017</td>
</tr>
<tr>
<td>Gore® Excluder®</td>
<td>W.L. Gore &amp; Associates</td>
<td>2002</td>
<td>P020004</td>
</tr>
<tr>
<td>Zenith® AAA Endovascular Graft</td>
<td>Cook</td>
<td>2003</td>
<td>P020018</td>
</tr>
<tr>
<td>Endologix Powerlink® (Afx Endovascular AAA system)</td>
<td>Endologix</td>
<td>2004</td>
<td>P040002</td>
</tr>
<tr>
<td>Talent® Abdominal Stent Graft System</td>
<td>Medtronic</td>
<td>2008</td>
<td>P070027</td>
</tr>
<tr>
<td>Endurant® II AAA Stent Graft System</td>
<td>Medtronic</td>
<td>2010</td>
<td>P100021</td>
</tr>
<tr>
<td>Valiant Thoracic Stent Graft System</td>
<td>Medtronic</td>
<td>2011</td>
<td>P100040</td>
</tr>
<tr>
<td>Relay Thoracic Stent-Graft with Plus Delivery System</td>
<td>Bolton Medical</td>
<td>2012</td>
<td>P110038</td>
</tr>
<tr>
<td>Ovation™ Abdominal Stent Graft System</td>
<td>TriVascular</td>
<td>2012</td>
<td>P120006</td>
</tr>
<tr>
<td>Aorfix™ AAA Flexible Stent Graft System</td>
<td>Lombard Medical</td>
<td>2013</td>
<td>P110032</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket approval.

**RATIONALE**

**Summary of Evidence**

For individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of 4 RCTs comparing EVAR with open repair for elective treatment of AAAs has indicated that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in mortality, outcomes at 5 years or longer have shown greater reintervention rates and endovascular mortality and comparable overall survival rates for EVAR and open repair. Thus, the early advantage of EVAR is offset by a higher rate of late complications over the long term. Based on these data, EVAR may be considered as an alternative to open surgery in patients who are candidates for both procedures. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have ruptured AAAs who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For patients with ruptured AAAs, evidence from 4 RCTs and a patient-level meta-analysis has indicated that short- and intermediate-term survival following EVAR is comparable with open repair. Evidence from RCTs and nonrandomized matched comparisons has shown that EVAR is associated with lower perioperative morbidity. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals who have AAAs ineligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. At least 2 RCTs have compared EVAR with no surgical intervention for patients ineligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials did not report superior outcomes with EVAR and thus do not support the use of EVAR in this population. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Cardiology Foundation and American Heart Association

Updated guidelines on the management of abdominal aortic aneurysms (AAAs) were released by the American College of Cardiology Foundation and the American Heart Association in 2011 as a focused update to the 2005 guidelines on the management of patients with peripheral artery disease.41 These guidelines made the following recommendations (see Table 2).

Table 2. Guidelines on Management of Patients with Peripheral Artery Disease

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good surgical candidates</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Periodic long-term surveillance imaging should be performed to monitor for endoleak, confirm graft position, document shrinkage or stability of the excluded aneurysm sac, and determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>Open aneurysm repair is reasonable to perform in patients who are good surgical candidates but who cannot comply with the periodic long-term surveillance required after endovascular repair</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Endovascular repair of infrarenal aortic aneurysms in patients who are at high surgical or anesthetic risk as determined by the presence of coexisting severe cardiac, pulmonary, and/or renal disease is of uncertain effectiveness</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

AAA: abdominal aortic aneurysm; COR: class of recommendation; LOE: level of evidence.

Professional guidelines from the American College of Cardiology and American Heart Association (2006), based on both randomized and nonrandomized trials, have suggested that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open surgeries.42

Society of Interventional Radiology

Guidelines on the use of endovascular aneurysm repair (EVAR) were developed by the Society of Interventional Radiology in 2010 and endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association.43 These guidelines indicated that:

"Indications for EVAR are currently the same as open repair...."

"Patient preference for EVAR versus open repair should be considered when appropriate...."

"Endovascular abdominal aortic aneurysm repair should be considered as having an intermediate to high cardiac risk that ranges from 3% to 7%.

There has been increasing use of EVAR for ruptured aneurysms. "Achieving optimal EVAR results for ruptured AAA requires establishment of a treatment protocol involving the emergency department, the endovascular team, anesthesiology, and the operating room personnel."

"Lifelong imaging surveillance of patients after EVAR is critical for (i) the detection and, if possible, the characterization of endoleaks; (ii) evidence of expansion or shrinkage of the residual AAA sac through measurement of aneurysm size, volume calculation, and identification of substantial changes..."
in aneurysm dimensions; (iii) detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture; and (iv) evaluation of the long-term performance of the endoprosthesis."

Society for Vascular Surgery
The Society for Vascular Surgery published guidelines for the treatment of AAAs in 2018. As in previous publications, these guidelines indicated that open surgery and EVAR are options for patients with aneurysms that meet the current treatment threshold. These guidelines also made the following recommendations (see Table 3).

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>QOE</th>
<th>LOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR is progressively replacing open surgery as the treatment of choice, and accounts for more than half of all elective AAA repairs in the United States</td>
<td>Moderate</td>
<td>Strong</td>
</tr>
<tr>
<td>Emergent EVAR should be considered for treatment of a ruptured AAA, if anatomically feasible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EVAR may be considered for high-risk patients unfit for surgical repair</td>
<td>Low</td>
<td>Weak</td>
</tr>
<tr>
<td>For patients with ruptured aneurysm, immediate repair is recommended</td>
<td>High</td>
<td>Strong</td>
</tr>
</tbody>
</table>


U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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**POLICY HISTORY**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy statement changed to not medically necessary. References 16, 17, 22, 27, 40, 42 added; remaining references reordered or removed.</td>
</tr>
<tr>
<td>September 2012</td>
<td>Update Policy</td>
<td>Policy updated with literature review, References added, no change to policy statement.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review through February 26, 2014. References 1-3, 25-27, 31-35, 48-49, and 59 added. The 2nd policy statement was editorially revised to clarify that situations that do not meet the criteria in the 1st policy statement would be considered not medically necessary.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review through March 9, 2015. References 47-48 and 56-57 were added. The policy statement is unchanged.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 22, 34, 37, and 50 added. Policy statements unchanged. Policy title changed to “Endovascular Stent Grafts for Abdominal Aortic Aneurysms.”</td>
</tr>
</tbody>
</table>
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