

# Protocol

## Endovascular Stent Grafts for Abdominal Aortic Aneurysms

(70167)

(Formerly Endovascular Grafts for Abdominal Aortic Aneurysms)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/15	<b>Next Review Date:</b> 09/17
<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/07, 07/08, 09/09, 03/10, 03/11, 03/12, 03/13, 01/14, 09/14, 09/15, 09/16	

### **Preauthorization is not required.**

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With abdominal aortic aneurysms eligible for open repair</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Endovascular stent grafts</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Open repair</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Overall survival</li><li>• Morbid events</li><li>• Treatment-related mortality</li><li>• Treatment-related morbidity</li></ul>
Individuals: <ul style="list-style-type: none"><li>• With ruptured abdominal aortic aneurysms</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Endovascular stent grafts</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Open repair</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Overall survival</li><li>• Morbid events</li><li>• Treatment-related mortality</li><li>• Treatment-related morbidity</li></ul>
Individuals: <ul style="list-style-type: none"><li>• With abdominal aortic aneurysms not eligible for open repair</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Endovascular stent grafts</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Non-surgical therapy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Overall survival</li><li>• Morbid events</li><li>• Treatment-related mortality</li><li>• Treatment-related morbidity</li></ul>

### **Description**

Endovascular 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.

### **Summary of Evidence**

In individuals who have abdominal aortic aneurysms (AAAs) eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. Evidence from RCTs comparing endovascular aneurysm repair (EVAR) with open repair for elective treatment of AAAs indicates that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in morbidity and mortality, trials

reporting outcomes at five years or longer have shown comparable survival rates for EVAR and open repair. Thus, the early advantage of EVAR is balanced out by a higher rate of late complications over the long term. In addition, one trial of patients at low-to-moderate surgical risk reported that the early benefit of EVAR was not evident in this population, raising the question of whether the early benefits of EVAR extend to patients at lower risk for open surgery. 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

In 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 morbidity and mortality. For patients with ruptured AAAs, evidence from four RCTs and a patient-level meta-analysis indicates 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

In individuals who have AAAs not eligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. At least two RCTs have compared EVAR to no surgical intervention in 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 use of EVAR in this population. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

### Policy

The use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) as a treatment of abdominal aortic aneurysms (AAAs) may be considered **medically necessary** as a treatment of AAAs 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 six months
- an aneurysmal diameter that measures twice the size of the normal infrarenal aorta
- a ruptured abdominal aortic aneurysm (see Policy Guidelines).

The use of endoprostheses approved by the FDA as a treatment of AAAs is considered **investigational** 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 AAA with endoprostheses, several factors must be considered including the following:

- The patient must be sufficiently stable to undergo detailed computed tomography (CT) examination for anatomic measurements,
- 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 either CT or ultrasonography every six to 12 months, or more frequently if perivascular leaks or aneurysm enlargement is detected.

### Background

Conventional management of clinically significant abdominal aortic aneurysms (AAAs) consists of surgical excision with placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate of 4%, which may rise to 10% in symptomatic patients. Due to this high mortality rate, endovascular prostheses have been investigated as a minimally invasive, catheter-based alternative to open surgical excision of AAAs. These devices are deployed across the aneurysm such that the aneurysm is effectively “excluded” from the circulation, with subsequent restoration of normal blood flow.

There are several types of grafts currently under investigation—straight grafts, in which both ends are anchored to the infrarenal aorta, and bifurcated grafts, in which the proximal end is anchored to the infrarenal aorta, and the distal ends are anchored to the iliac arteries. Recently, fenestrated grafts have also been investigated. These grafts are designed with openings in the wall that can be placed across the renal or celiac arteries while still protecting vessel patency through these critical arteries. In addition, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal.

### Regulatory Status

A large number of endovascular grafts have been approved for use for treatment of AAAs by the U.S. Food and Drug Administration (FDA) through the pre-market approval process:

- The EVT Abdominal Aortic Endovascular Grafting System (1999, Guidant Endovascular Technologies). In the Guidant system, the endograft is placed in the aorta and expanded using balloon dilation. The graft is anchored to the vessel wall using sutureless hooks at its superior and inferior ends.
- The AneuRx® Prosthesis System (1999, now called AneuRx AAA Advantage Stent Graft; Medtronic Vascular). The AneuRx system consists of a woven polyester interior surface with a self-expanding nitinol exoskeleton. The radial force of the expanding stent embeds the exoskeleton into the aneurysm wall and thus constitutes the attachment mechanism.
- In April 2002, an additional Guidant device, the Ancure® Aortoiliac System, was approved by FDA. The Ancure device consists of a woven polyester graft that is housed within a long flexible delivery tube (catheter) for use in patients whose anatomy is not suited for the use of the single tube or bifurcated endograft device. This version is identical to the earlier Guidant Endovascular Grafting System except that the aortoiliac Ancure grafts have suture loops on the superior and inferior attachment systems.
- The Gore® Excluder® (2002)
- The Zenith® AAA Endovascular Graft (2003; now called Zenith Flex AAA Endovascular Graft)
- The Endologix Powerlink® (2004)
- The Medtronic Talent® Abdominal Stent Graft System (2008)
- The Medtronic Vascular Endurant® II AAA Stent Graft System (2010)<sup>1</sup>
- The Endologix AFX® endovascular system (2011)

- The Ovation™ Abdominal Stent Graft System (2012, TriVascular Inc.), a lower-profile stent graft that uses a postimplantation polymer deployment system to seal the device to the aorta, was approved by FDA for endovascular repair of AAAs with suitable anatomy<sup>2</sup>
- The Zenith® Fenestrated AAA Endovascular Graft (2012, Cook Medical), a graft that extends across the visceral arteries, was approved by FDA with the adjunctive Zenith Alignment Stent. The graft is approved for endovascular treatment of aortic or aortoiliac aneurysms that are suitable for endovascular repair with the following:
  - “Adequate iliac/femoral access compatible with required introduction systems
  - Nonaneurysmal infrarenal aortic segment (neck) proximal to the aneurysms with:
    - Length  $\geq$  4 mm and unsuitable for a nonfenestrated graft
    - Diameter  $\leq$  31 mm and  $\geq$  19 mm
    - $<$  45 degrees relative to long axis of aneurysm
    - Angle  $<$  45 degrees relative to axis of suprarenal aorta
  - Ipsilateral iliac artery fixation site  $>$  30 mm in length and between nine and 21 mm in diameter
  - Contralateral iliac artery distal fixation site  $>$  30 mm in length and between seven and 21 mm in diameter.”
- The Aorfix™ AAA Flexible Stent Graft System (2013, Lombard Medical).<sup>3</sup>  
FDA product code MIH.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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