

# Protocol

## Endovascular Stent Grafts for Abdominal Aortic Aneurysms

(70167)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/15	<b>Next Review Date:</b> 09/20
<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, 09/17, 09/18, 09/19	

### ***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.*

<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
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 ineligible 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>• Nonsurgical 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 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.

### **SUMMARY OF EVIDENCE**

For individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and nonrandomized comparative studies. Relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of four RCTs comparing endovascular aneurysm repair (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 five years or longer have shown greater reintervention rates and endovascular mortality and comparable OS 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, and nonrandomized comparative studies. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For patients with ruptured AAAs, evidence from four 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 OS, morbid events, and treatment-related mortality and morbidity. At least two 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.

## 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** in any of the following clinical situations:

- an aneurysmal diameter greater than five cms
- an aneurysmal diameter of four to five cms 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 AAA (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 are detected.

## BACKGROUND

Conventional management of a clinically significant abdominal aortic aneurysm (AAA) consists of surgical excision with the placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate between 1% and 5%. Perioperative morbidity and mortality are highest in older female patients with cardiac, pulmonary, or kidney disease; the most common cause of death is multisystem organ failure.

Due to the high mortality rate, endovascular prostheses have been developed as a less risky and 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.

The main potential advantage of endovascular grafts for an AAA is that they offer a less invasive and less risky approach to the repair of abdominal aneurysms. While the use of an endovascular approach has the potential to reduce the relatively high perioperative morbidity and mortality associated with open AAA repair, use of endovascular grafts also has potential disadvantages. In particular, there are concerns about the durability of the anchoring system, aneurysm expansion, and other late complications related to the prosthetic graft. Aneurysm expansion may result from perivascular leaks, also known as endoleaks, which are a unique complication of endoprotheses. Perivascular leaks may result from an incompetent seal at one of the graft attachment sites, blood flow in aneurysm tributaries (these tributaries are ligated during open surgery), or perforation of graft fabric.<sup>1-4</sup>

Several types of grafts are currently in use: 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. 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. Also, 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 by the U.S. Food and Drug Administration 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. Food and Drug Administration product code MIH.

Table 1. Abdominal Aortic Stent Grafts Approved by FDA

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

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

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.

1. Blum U, Voshage G, Lammer J, et al. Endoluminal stent-grafts for infrarenal abdominal aortic aneurysms. *N Engl J Med.* Jan 2 1997;336(1):13-20. PMID 8970935
2. Ernst CB. Current therapy for infrarenal aortic aneurysms. *N Engl J Med.* Jan 2 1997;336(1):59-60. PMID 8970942
3. White RA, Donayre CE, Walot I, et al. Modular bifurcation endoprosthesis for treatment of abdominal aortic aneurysms. *Ann Surg.* Sep 1997;226(3):381-389; discussion 389-391. PMID 9339944
4. Zarins CK, White RA, Schwarten D, et al. AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. *J Vasc Surg.* Feb 1999;29(2):292-305; discussion 306-298. PMID 9950987
5. Blue Cross and Blue Shield Association. Endovascular Stent-Grafts for Abdominal Aortic Aneurysm Repair. TEC Assessment Program. 2001;16(2).
6. Greenhalgh RM, Brown LC, D. E, et al. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. *Lancet.* Jun 25-Jul 1 2005;365(9478):2179-2186. PMID 15978925
7. Blankensteijn JD, de Jong SE, Prinssen M, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med.* Jun 9 2005;352(23):2398-2405. PMID 15944424
8. Greenhalgh RM, Brown LC, Epstein D, et al. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomised controlled trial. *Lancet.* Jun 25-Jul 1 2005;365(9478):2187-2192. PMID 15978926
9. Greenhalgh RM, Brown LC, Kwong GP, et al. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. *Lancet.* Sep 4-10 2004;364(9437):843-848. PMID 15351191
10. Prinssen M, Verhoeven EL, Buth J, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *N Engl J Med.* Oct 14 2004;351(16):1607-1618. PMID 15483279
11. Anderson PL, Arons RR, Moskowitz AJ, et al. A statewide experience with endovascular abdominal aortic aneurysm repair: rapid diffusion with excellent early results. *J Vasc Surg.* Jan 2004;39(1):10-19. PMID 14718804
12. Hua HT, Cambria RP, Chuang SK, et al. Early outcomes of endovascular versus open abdominal aortic aneurysm repair in the National Surgical Quality Improvement Program-Private Sector (NSQIP-PS). *J Vasc Surg.* Mar 2005;41(3):382-389. PMID 15838467

13. Lee WA, Carter JW, Upchurch G, et al. Perioperative outcomes after open and endovascular repair of intact abdominal aortic aneurysms in the United States during 2001. *J Vasc Surg.* Mar 2004;39(3):491-496. PMID 14981436
14. Paravastu SC, Jayarajasingam R, Cottam R, et al. Endovascular repair of abdominal aortic aneurysm. *Cochrane Database Syst Rev.* Jan 23 2014;1(1):CD004178. PMID 24453068
15. Powell JT, Sweeting MJ, Ulug P, et al. Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years. *Br J Surg.* Feb 2017;104(3):166-178. PMID 28160528
16. Biancari F, Catania A, D'Andrea V. Elective endovascular vs. open repair for abdominal aortic aneurysm in patients aged 80 years and older: systematic review and meta-analysis. *Eur J Vasc Endovasc Surg.* Nov 2011; 42(5):571-576. PMID 21820922
17. Ulug P, Sweeting MJ, von Allmen RS, et al. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis. *Lancet.* Jun 24 2017;389(10088):2482-2491. PMID 28455148
18. Lederle FA, Freischlag JA, Kyriakides TC, et al. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. *N Engl J Med.* Nov 22 2012;367(21):1988-1997. PMID 23171095
19. De Bruin JL, Baas AF, Buth J, et al. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. *N Engl J Med.* May 20 2010;362(20):1881-1889. PMID 20484396
20. Greenhalgh RM, Brown LC, Powell JT, et al. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med.* May 20 2010;362(20):1863-1871. PMID 20382983
21. Brown LC, Thompson SG, Greenhalgh RM, et al. Incidence of cardiovascular events and death after open or endovascular repair of abdominal aortic aneurysm in the randomized EVAR trial 1. *Br J Surg.* Jul 2011;98(7): 935-942. PMID 21484775
22. Becquemin JP, Pillet JC, Lesclapier F, et al. A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients. *J Vasc Surg.* May 2011; 53(5):1167-1173 e1161. PMID 21276681
23. Schermerhorn ML, Buck DB, O'Malley AJ, et al. Long-term outcomes of abdominal aortic aneurysm in the Medicare population. *N Engl J Med.* Jul 23 2015;373(4):328-338. PMID 26200979
24. Liang NL, Reitz KM, Makaroun MS, et al. Comparable perioperative mortality outcomes in younger patients undergoing elective open and endovascular abdominal aortic aneurysm repair. *J Vasc Surg.* May 2018;67(5): 1404-1409 e1402. PMID 29097041
25. Krenzien F, Matia I, Wiltberger G, et al. Outcome after open surgery repair in endovascular-suitable patients with ruptured abdominal aortic aneurysms. *Vasa.* Nov 2013;42(6):442-448. PMID 24220121
26. Sweeting MJ, Balm R, Desgranges P, et al. Individual-patient meta-analysis of three randomized trials comparing endovascular versus open repair for ruptured abdominal aortic aneurysm. *Br J Surg.* Sep 2015; 102(10):1229-1239. PMID 26104471
27. Badger S, Forster R, Blair PH, et al. Endovascular treatment for ruptured abdominal aortic aneurysm. *Cochrane Database Syst Rev.* May 26 2017;5:CD005261. PMID 28548204
28. IMPROVE Trial Investigators, Powell JT, Sweeting MJ, et al. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial. *BMJ.* Jan 13 2014;348:f7661. PMID 24418950
29. IMPROVE Trial Investigators. Endovascular strategy or open repair for ruptured abdominal aortic aneurysm: one-year outcomes from the IMPROVE randomized trial. *Eur Heart J.* Aug 14 2015;36(31):2061-2069. PMID 25855369
30. Reimerink JJ, Hoornweg LL, Vahl AC, et al. Endovascular repair versus open repair of ruptured abdominal aortic aneurysms: a multicenter randomized controlled trial. *Ann Surg.* Aug 2013;258(2):248-256. PMID 23549424

31. Desgranges P, Kobeiter H, Katsahian S, et al. ECAR (Endovasculaire ou Chirurgie dans les Aneurysmes aorto-iliaques Rompus): A French randomized controlled trial of endovascular versus open surgical repair of ruptured aorto-iliac aneurysms. *Eur J Vasc Endovasc Surg*. Sep 2015;50(3):303-310. PMID 26001320
32. Edwards ST, Schermerhorn ML, O'Malley AJ, et al. Comparative effectiveness of endovascular versus open repair of ruptured abdominal aortic aneurysm in the Medicare population. *J Vasc Surg*. Mar 2014;59(3):575-582. PMID 24342064
33. Filardo G, Powell JT, Martinez MA, et al. Surgery for small asymptomatic abdominal aortic aneurysms. *Cochrane Database Syst Rev*. Mar 14 2012;3(3):CD001835. PMID 22419281
34. Cao P, De Rango P, Verzini F, et al. Comparison of surveillance versus aortic endografting for small aneurysm repair (CAESAR): results from a randomised trial. *Eur J Vasc Endovasc Surg*. Jan 2011;41(1):13-25. PMID 20869890
35. Ouriel K, Clair DG, Kent KC, et al. Endovascular repair compared with surveillance for patients with small abdominal aortic aneurysms. *J Vasc Surg*. May 2010;51(5):1081-1087. PMID 20304589
36. De Rango P, Verzini F, Parlani G, et al. Quality of life in patients with small abdominal aortic aneurysm: the effect of early endovascular repair versus surveillance in the CAESAR trial. *Eur J Vasc Endovasc Surg*. Mar 2011;41(3):324-331. PMID 21145269
37. Greenhalgh RM, Brown LC, Powell JT, et al. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. *N Engl J Med*. May 20 2010;362(20):1872-1880. PMID 20382982
38. Wilt TJ, Lederle FA, Macdonald R, et al. Comparison of endovascular and open surgical repairs for abdominal aortic aneurysm. *Evid Rep Technol Assess (Full Rep)*. Aug 2006(144):1-113. PMID 17764213
39. Sweeting MJ, Patel R, Powell JT, et al. Endovascular repair of abdominal aortic aneurysm in patients physically ineligible for open repair: very long-term follow-up in the EVAR-2 randomized controlled trial. *Ann Surg*. Nov 2017;266(5):713-719. PMID 28742684
40. Rooke TW, Hirsch AT, Misra S, et al. 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. Nov 1 2011;58(19):2020-2045. PMID 21963765
41. Hirsch AT, Haskal ZJ, Hertzner NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease) endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *J Am Coll Cardiol*. Mar 21 2006;47(6):1239-1312. PMID 16545667
42. Walker TG, Kalva SP, Yeddula K, et al. Clinical practice guidelines for endovascular abdominal aortic aneurysm repair: written by the Standards of Practice Committee for the Society of Interventional Radiology and endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association. *J Vasc Interv Radiol*. Nov 2010;21(11):1632-1655. PMID 20884242
43. Chaikof EL, Dalman RL, Eskandari MK, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg*. Jan 2018;67(1):2-77.e72. PMID 29268916