Protocol

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

(70167)

Medical Benefit		**Effective Date**: 01/01/15	**Next Review Date**: 09/19
Preauthorization	No	**Review Dates**: 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	

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: • With abdominal aortic aneurysms eligible for open repair	Interventions of interest are: • Endovascular stent grafts	Comparators of interest are: • Open repair	Relevant outcomes include: • Overall survival • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With ruptured abdominal aortic aneurysms	Interventions of interest are: • Endovascular stent grafts	Comparators of interest are: • Open repair	Relevant outcomes include: • Overall survival • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With abdominal aortic aneurysms ineligible for open repair	Interventions of interest are: • Endovascular stent grafts	Comparators of interest are: • Nonsurgical therapy	Relevant outcomes include: • Overall survival • Morbid events • Treatment-related mortality • Treatment-related morbidity

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) 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 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 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 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 overall survival, 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 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 endoprostheses. 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.[1-4]

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 (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

Stent Name	PMA Applicant	Approved	PMA No.
AneuRx® Prosthesis System (AneuRx AAAdvantage Stent Graft)	Medtronic Vascular	1999	P990020
Ancure® Aortoiliac System	Guidant Endovascular Technologies	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	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.

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