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*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** 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.*

Description

Endovascular grafts are 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.

Background

The conventional management of a clinically significant abdominal aortic aneurysm (AAA) 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.

In 1999, the U.S. Food and Drug Administration (FDA) approved two endovascular grafts for use in the abdominal aorta: the EVT Abdominal Aortic Endovascular Grafting System (Guidant Endovascular Technologies) and the AneuRx® Prosthesis System (now called AneuRx AAAAdvantage Stent Graft - Medtronic Vascular, Inc.). 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 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, the FDA approved an additional Guidant device, the Ancure® Aortoiliac System. 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. Several other grafts have been subsequently approved, including the Gore® Excluder® (2002), the Zenith® AAA Endovascular Graft (2003 – now called Zenith

Flex AAA Endovascular Graft), the Endologix Powerlink® (2004), and the Medtronic Talent® Abdominal Stent Graft System (2008).

The Zenith® Fenestrated AAA Endovascular Graft, a graft that extends across the visceral arteries, was approved by the FDA with the adjunctive Zenith Alignment Stent in April 2012. The device is approved for endovascular treatment of aortic or aortoiliac aneurysms which 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 4 mm and unsuitable for a non-fenestrated graft
 - Diameter < 31 mm and 19 mm
 - Angle < 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 9 - 21 mm in diameter
- Contralateral iliac artery distal fixation site > 30 mm in length and between 7 - 21 mm in diameter.”

Policy (Formerly Corporate Medical Guideline)

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

- an aneurysmal diameter greater than 5.0 cm
- an aneurysmal diameter of 4-5.0 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 abdominal aortic aneurysms is considered **investigational** for 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 medical limitations or other factors.

Policy Guideline

For treatment of ruptured abdominal aortic aneurysm 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 computed tomography or ultrasonography every six to 12 months, or more frequently if perivascular leaks or aneurysm enlargement is detected.

Medicare Advantage

Endovascular repair using prosthesis will be considered **medically necessary** for treatment of patients with abdominal aortic or aortoiliac aneurysm having morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with required introduction systems
- Nonaneurysmal infrarenal aortic segment (neck) proximal to the aneurysms with:
 - Length > 4 mm and unsuitable for a non-fenestrated graft
 - Diameter < 31 mm and > 19 mm
 - Angle < 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 9-21 mm in diameter
- Contralateral iliac artery distal fixation site > 30 mm in length and between 7-21 mm in diameter

Only grafts and/or stents approved by the FDA should be used.

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.**

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

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