

Corporate Medical Policy

Endovascular Stent Grafts for Abdominal Aortic Aneurysm

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Description of Procedure or Service

The conventional management of a clinically significant abdominal aortic aneurysm 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 abdominal aortic aneurysms. 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 EBT 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).

Grafts that extend across the visceral arteries are currently under development, but are not FDA approved. For example, the Zenith Fenestrated AAA Endovascular Graft is currently under investigation as part of the FDA approval process.

Although initial endovascular grafting may be successful, a small risk of aneurysm rupture due to late failure of the endograft still remains. Periodic monitoring for endoleak and sac dilation is done

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with contrast enhanced CT scan, MRI or ultrasound. In order to reduce the risk of rupture and the frequency of imaging, endosensors are being developed that will provide for monitoring of aortic aneurysm pressure after endovascular repair. A sensor device is inserted during the same procedure as the endovascular stent graft and is positioned next to the graft within the aneurysm sac. Pressure measurements are transmitted via radiofrequency to a device that is held over the patient's body.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Endovascular Stent Grafts for Abdominal Aortic Aneurysms when they are determined to be medically necessary because the medical criteria and guidelines shown below have been met.

BCBSNC will not provide coverage for implanted pressure sensors for detection of endoleaks in the aneurysmal sac following endovascular repair because they are considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Endovascular Stent Grafts for Abdominal Aortic Aneurysm are covered

- A. Endovascular Stent Grafts for Abdominal Aortic Aneurysms are covered when any of the following criteria are met:
 1. the diameter of the abdominal aortic aneurysm measures equal to or greater than 5 cm.
 2. the aneurysmal diameter of 4-5cm has increased in size by 0.5cm in the last 6 months.
 3. the abdominal aortic aneurysm measures twice the diameter of the normal aorta at the infrarenal neck.
 4. A ruptured abdominal aneurysm. For treatment of ruptured abdominal aortic aneurysm with endoprostheses, several factors must be considered, including the following:
 - a. The patient must be sufficiently stable to undergo detailed CT examination for anatomic measurements,
 - b. The aneurysm should be anatomically appropriate for endovascular repair, and
 - c. Specialized personnel should be available.
- B. Endovascular Stent Grafts for Iliac Aneurysms are covered for iliac artery aneurysms greater than 3 cm in patients with appropriate aortoiliac anatomy.

When Endovascular Stent Grafts for Abdominal Aortic Aneurysm are not covered

The use of abdominal endovascular stent grafts is considered investigational for all other indications not noted above. The use of non-FDA approved endovascular stent graft devices is also

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considered investigational.

BCBSNC will not provide coverage for implanted intrasac pressure sensors for detection of endoleaks in the aneurysmal sac following endovascular repair because they are considered investigational.

Policy Guidelines

Endovascular repair can be done safely with post-operative recovery in the intensive care unit rarely required. These patients are usually discharged home sooner than patients undergoing open surgical repair. Major cardiopulmonary complications also occur less frequently. In addition, there appears to be a decrease in blood transfusion requirements, hospital length of stays and intensive care monitoring. Patients generally return to pre-intervention levels of activity more rapidly. Current recommendations for the repair of AAA in intermediate to high surgical risk patients support the use of endovascular repair.

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).

At this time, there are inadequate published data on implantable intrasac pressure sensors to permit conclusions concerning long-term safety and efficacy of this technology. (Refer to separate BCBSNC policy titled, Investigational (Experimental) Services.)

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0078T, 0079T, 0080T, 0081T, 0254T, 0255T, 34800, 34802, 34803, 34804, 34805, 34806, 34808, 34812, 34813, 34820, 34825, 34826, 34900, 93982

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

For Policy titled: Endovascular Grafts for Abdominal Aortic Aneurysm

Medical Policy Reference Manual 7/10/98

Harris PL. The highs and lows of endovascular aneurysm repair: the first two years of the Eurostar Registry. *Ann R Coll Surg Engl.* 1999;81(3):161-5.

White GH, May J, Waugh R. Shortening of endografts during deployment in endovascular AAA repair. *J Endovasc Surg.* 1999;6(1):4-10.

Specialty Matched Consultant Advisory Panel 11/99

Medical Policy Advisory Group 12/99

A search of literature was completed through MEDLINE database for the period from January 1997 through March 2000. The search strategy focused on references containing the key words: endovascular grafts, abdominal aortic aneurysms, endovascular.

Medical Policy Reference Manual - 2/18/00

Medical Policy Advisory Group approved 4/20/00

Specialty Matched Consultant Advisory Panel - 8/2000

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual, 7.01.67; 5/31/01

Specialty Matched Consultant Advisory Panel -9/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.67, 04/29/03

ECRI Comprehensive Technology Assessment Executive Summary (2004, April) Endovascular grafts for prophylactic abdominal aortic aneurysm repair. Retrieved April 21, 2004 from http://www.ta.ecri.org/Comp_Tech/Prod/summary/detail.

Specialty Matched Consultant Advisory Panel - 6/2004

For Policy renamed: Endovascular Stent Graft for Aortic Aneurysm

Canadian Ministry of Health and Long-Term Care Medical Advisory Secretariat (2005, July). Interim Report on Endovascular Repair of Abdominal Aortic Aneurysms. Retrieved November 21, 2005, from http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/sum_evar_070105.html

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.86, 6/27/05.

U.S. Food and Drug Administration. Center for Devices and Radiological Health. GORE TAG Thoracic Endoprosthesis. Retrieved November 21, 2005 from <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=12328>

National Institute for Health and Clinical Excellence (NICE). Endovascular stent-graft placement in thoracic aortic aneurysms and dissections. *Interventional Procedures Guidance 127*. London, UK: NICE; 2005 June. Retrieved November 21, 2005 from <http://www.nice.org.uk/ipcat.aspx?c=54195>

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ECRI Custom Hotline Response (2006, January) Implantable Intrasac Pressure Sensor for Monitoring During Endovascular Repair of Abdominal Aortic Aneurysms. Retrieved February 20, 2006, from http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?e=6&doc_id=9103

Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine and Biology, and the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2006;47(6):1239-1312. Retrieved 1/9/07 from <http://content.onlinejacc.org/cgi/reprint/47/6/1239>

Wilt TJ, Lederle FA, MacDonald R, Jonk YC, Rector TS, Kane RL. Comparison of Endovascular and Open Surgical Repairs for Abdominal Aortic Aneurysm. Evidence Report/Technology Assessment No. 144. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.) AHRQ Publication No. 06-E017. Rockville, MD. Agency for Healthcare Research and Quality. August 2006. Retrieved 12/27/07 from <http://www.ahrq.gov/clinic/tp/aaareptp.htm>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.67, 2/15/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.86, 7/20/06

McPhee J., Eslami M.H., Arous E.J., et al. Endovascular Treatment for Ruptured Abdominal Aortic Aneurysms in the United States (2001-2006): A Significant Survival Benefit Over Open Repair is Independently Associated with Increased Institutional Volume, *Journal of Vascular Surgery* 2009; Vol. 49, No. 4, 817-826

Egorova N., Giacomelli J., Greco G., et al. National Outcomes for the Treatment of Ruptured Abdominal Aortic Aneurysms: Comparison of Open Versus Endovascular Repairs, *Journal of Vascular Surgery* 2008; Vol. 48, No. 5, 1092-1100

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.86, 9/10/09

BCBSA Medical Policy Reference manual [Electronic Version] 7.01.67, 2/11/2010

BCBSA Medical Policy Reference Manual [Electronic Version] 7.01.111, 9/10/09

Specialty Matched Consultant Advisory Panel 6/2010

For Policy re-titled: Endovascular Stent Grafts for Abdominal Aortic Aneurysm

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.67, 2/11/2010

Food and Drug Administration (FDA). Pre-market Approval for Ancure Aortoiliac System. Retrieved on February 11, 2011 from http://www.accessdata.fda.gov/cdrh_docs/pdf/P990017S030a.pdf

Food and Drug Administration (FDA). Pre-market Approval for Zenith Flex AAA Endovascular Graft. Retrieved on February 11, 2011 from http://www.accessdata.fda.gov/cdrh_docs/pdf2/p020018a.pdf

Food and Drug Administration (FDA). Pre-market Approval for Endologix Powerlink. Retrieved on February 11, 2011 from http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040002a.pdf

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De Bruin JL, Baas AF, Buth J et al. Long-term outcomes of open or endovascular repair of abdominal aortic aneurysm. N Engl J Med 2010; 362(20):1881-9.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.67, 4/14/11

Medical Director review 4/2011

Specialty Matched Consultant Advisory Panel review 6/2011

Policy Implementation/Update Information

For Policy titled: Endovascular Grafts for Abdominal Aortic Aneurysm

- 6/99 Policy implemented. Literature review indicates that the procedure should be investigational.
- 7/99 Reformatted, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 5/00 Procedure changed from investigational to covered when listed criteria are met. MPAG approved on 4/20/00. System coding changes.
- 8/00 Specialty Matched Consultant Advisory Panel. No change in criteria
- 9/00 System coding changes.
- 10/00 Medical Policy Advisory Group review. No changes to criteria. Approve
- 12/00 New 2001 CPT codes 34800-34826, 75952 and 75953 added. System coding changes.
- 8/01 Revised statement #2 under "when it is covered" section.
- 9/02 Specialty Matched Consultant Advisory Panel. No change in criteria.
- 1/03 Added code 34900 and 75954 to policy. Removed code 37250 from policy. System coding changes.
- 3/04 Benefits Application and Billing/Coding sections updated for consistency.
- 7/29/04 Specialty Matched Consultant Advisory Panel review 06/08/2004 with no changes in criteria. References added. Codes 0001T and 34805 added to Billing/Coding section. The phrase "Codes closely related to this service are" was removed from the policy. Codes 37205, 75954, and 75960 removed from policy.
- 1/6/05 Codes 0078T, 0079T, 0080T, 0081T, 34803 added to Billing/Coding section of policy.

For Policy renamed: Endovascular Stent Grafts for Aortic Aneurysm

- 3/30/06 Specialty Matched Consultant Advisory Panel review 2/27/06. Name of policy changed to "Endovascular Stent Graft for Aortic Aneurysm" from "Endovascular Grafts for Abdominal Aortic Aneurysm". New indication added to "When Covered" section; "B. Endovascular stent grafts for thoracic aortic aneurysms may be considered medically necessary for the treatment of descending thoracic aortic aneurysms of 23-37 mm of inner aortic diameter". New information added the "When Not Covered" section

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indicating; "BCBSNC will not provide coverage for implanted intrasac pressure sensors for detection of endoleaks in the aneurysmal sac following endovascular repair because they are considered investigational". Rationale added to "Policy Guidelines" section. CPT Codes and references updated.

- 12/31/07 Coding update. Delete CPT Codes 0153T and 0154T and replace with 34806 and 93982. (adn)
- 4/21/08 Information regarding Iliac Artery Aneurysms added to Description section. Statement added to the Covered section that reads: Endovascular Stent Grafts for Iliac Aneurysms are covered for iliac artery aneurysms greater than 3 cm in patients with appropriate aortoiliac anatomy. Added CPT code 34900 to Billing/Coding section. References updated. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn)
- 8/17/2010 Specialty Matched Consultant Advisory Panel review 6/2010. Removed Medical Policy number. Description section revised. Statement added to the When Covered section that reads: "4. A ruptured abdominal aneurysm. For treatment of ruptured abdominal aortic aneurysm with endoprostheses, several factors must be considered including the following: a. The patient must be sufficiently stable to undergo detailed CT examination for anatomic measurements, b. The aneurysm should be anatomically appropriate for endovascular repair, and c. Specialized personnel should be available." Policy Guidelines updated. References updated. Added new CPT codes 0254T and 0255T. (mco)

For Policy re-titled: Endovascular Stent Grafts for Abdominal Aortic Aneurysm

- 5/10/11 New policy implemented. The policy titled, "Endovascular Stent Graft for Aortic Aneurysm" has been split into policies specific to **thoracic** aortic aneurysm and **abdominal** aortic aneurysm. Endovascular Stent Grafts for Abdominal Aortic Aneurysms are covered when any of the following criteria are met: 1. the diameter of the abdominal aortic aneurysm measures equal to or greater than 5 cm. 2. the aneurysmal diameter of 4-5cm has increased in size by 0.5cm in the last 6 months. 3. the abdominal aortic aneurysm measures twice the diameter of the normal aorta at the infrarenal neck. 4. A ruptured abdominal aneurysm. For treatment of ruptured abdominal aortic aneurysm with endoprostheses, several factors must be considered, including the following: a.The patient must be sufficiently stable to undergo detailed CT examination for anatomic measurements, b.The aneurysm should be anatomically appropriate for endovascular repair, and c.Specialized personnel should be available. Endovascular Stent Grafts for Iliac Aneurysms are covered for iliac artery aneurysms greater than 3 cm in patients with appropriate aortoiliac anatomy. References updated. Medical Director review 4/2011.(mco)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy statements.(mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.