

## Corporate Medical Policy

### Endovascular Stent Grafts for Thoracic Aortic Aneurysm

<b>File Name:</b>	endovascular_stent_grafts_for_thoracic_aortic_aneurysm
<b>Origination:</b>	4/2011
<b>Last CAP Review:</b>	6/2011
<b>Next CAP Review:</b>	6/2012
<b>Last Review:</b>	6/2011

#### Description of Procedure or Service

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Aortic aneurysms are arterial dilations and are associated with age, atherosclerosis and hypertension, as well as some congenital connective tissue disorders. The likelihood of significant sequelae of aortic aneurysm is dependent on location, size, and underlying disease state. Left untreated, these aneurysms tend to enlarge over time, increasing the risk of rupture or dissection. Of greatest concern is the tendency for aortic aneurysms to rupture, with severe consequences including death. Another significant adverse occurrence of aortic aneurysm is aortic dissection, in which an intimal tear permits blood to enter the potential space between the intima and the muscular wall of the aorta. Stable dissections may be managed medically; however dissections which impinge on the true lumen of the aorta, or occlude branching vessels are a surgical emergency.

Thoracic endovascular aneurysm repair (TEVAR) has been investigated as an alternative to open surgical repair in patients in need of emergency surgery for rupture or dissection, as well as prophylactic treatment of aneurysm for those with a significant risk of future rupture or dissection. The standard open surgery technique for thoracic aortic aneurysm is open operative repair with graft replacement of the diseased segment. This procedure requires lateral thoracotomy, use of cardiopulmonary bypass, long operative times, and is associated with a variety of peri- and postoperative complications, with spinal cord ischemia considered the most devastating.

Aortic dissection can be subdivided into Type A, which involves the aortic arch, and Type B, which is confined to the descending aorta. Type A dissections are usually treated surgically, while Type B dissections are usually treated medically, with surgery indicated for serious complications, such as visceral ischemia, impending rupture, intractable pain, or sudden reduction in aortic size. Dissections associated with obstruction and ischemia can also be subdivided into an obstruction caused by an intimal tear at branch vessel orifices, or by compression of the true lumen by the pressurized false lumen. It has been proposed that endovascular therapy can repair the latter group of dissections by redirecting flow into the true lumen. The success of endovascular stent grafts of abdominal aortic aneurysms has created interest in applying the same technology to the aneurysms and dissections of the descending or thoraco-abdominal aorta.

In March 2005, the GORE TAG® Thoracic Endoprosthesis was approved by the FDA through the premarket approval process for endovascular repair of aneurysms of the descending thoracic aorta. Use of this device requires patients to have adequate iliac/femoral access, aortic inner diameter in the range of 23–37 mm, and  $\geq 2$  cm non-aneurysmal aorta proximal and distal to the aneurysm.

In May 2008, the Zenith TX2® TAA Endovascular Graft was approved by the FDA through the PMA process for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta. Indicated aortic inner diameter is in the range of 24–38 mm.

In June 2008, the Talent™ Thoracic Stent Graft System was approved by the FDA through the PMA

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process for the endovascular repair of fusiform and saccular aneurysms/penetrating ulcers of the descending thoracic aorta. Indicated aortic inner diameter is in the range of 18 - 42mm.

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 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.

Please see policy titled, "Endovascular Stent Grafts for Abdominal Aortic Aneurysms" for review of abdominal aortic grafting.

***\*\*\*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

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**Endovascular stent grafts may be considered medically necessary for the treatment of descending thoracic aortic aneurysms using devices approved by the U.S. Food and Drug Administration for their approved specifications.**

**Use of non-FDA approved stent grafts or use of grafts outside of the approved specifications is considered investigational**

**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

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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 Thoracic Aortic Aneurysm are covered

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Endovascular stent grafts may be considered medically necessary for the treatment of descending thoracic aortic aneurysms using devices approved by the U.S. Food and Drug Administration for their approved specifications.

Endograft placement relies on non-aneurysmal aortic segments proximal and distal to the aneurysm and/or dissection for anchoring, and a maximal graft diameter that varies by device.

- The GORE TAG® endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for ">2 cm non-aneurysmal aorta proximal and distal to the aneurysm and an "aortic inner diameter of 23–37 mm."
- The Talent™ Thoracic Stent Graft System is approved by the FDA for "non-aneurysmal aortic proximal and distal neck lengths >20mm" and "non-aneurysmal aortic diameter in the range of 18–42 mm."

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- The Zenith 2X2® device is approved by the FDA for non-aneurysmal aortic segments “of at least 25 mm in length” and “diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm.”

### When Endovascular Stent Grafts for Thoracic Aortic Aneurysm are not covered

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Use of non-FDA approved stent grafts or use of grafts outside of the approved specifications is 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

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Endovascular stenting is being evaluated as an alternative treatment to surgical or medical therapy for thoracic aortic aneurysms, acute and chronic dissections and traumatic aortic tears. There are no randomized trials of stenting versus alternative treatments to provide high-quality evidence of the efficacy of one approach over another for aneurysms or acute dissections. However, multiple non-randomized studies suggest that for elective repair of descending thoracic aortic aneurysms, stenting is associated with lower short-term mortality and lower complication rates compared to open surgery.

In 2010, a joint task force published guidelines on the diagnosis and management of descending thoracic and thoracoabdominal aortic aneurysms. The task force consisted of the American College of Cardiology Foundation, American Heart Association, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. The task force offered the following Class I recommendations:

- For patients with chronic dissection, particularly if associated with a connective tissue disorder, but without significant comorbid disease, and a descending thoracic aortic diameter exceeding 5.5 cm, open repair is recommended.
- For patients with degenerative or traumatic aneurysms of the descending thoracic aorta exceeding 5.5 cm, saccular aneurysms, or postoperative pseudoaneurysms, endovascular stent grafting should be strongly considered when feasible.
- For patients with thoracoabdominal aneurysms, in whom endovascular stent graft options are limited and surgical morbidity is elevated, elective surgery is recommended if the aortic diameter exceeds 6.0 cm, or less if a connective tissue disorder such as Marfan or Loeys-Dietz syndrome is present.
- For patients with thoracoabdominal aneurysms and with end-organ ischemia or significant stenosis from atherosclerotic visceral artery disease, an additional revascularization procedure is recommended.

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.

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## Billing/Coding/Physician Documentation Information

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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.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 33880, 33881, 33883, 33884, 33886, 33889, 33891, 34806, 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.

## Scientific Background and Reference Sources

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Hiratzka LF, Bakris GL, Beckman JA et al. 2010 Guidelines for the diagnosis and management of patients with thoracic aortic disease. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. *J Am Coll Cardiol* 2010; 55(14):e27-e129. Retrieved on February 11, 2011 from <http://circ.ahajournals.org/cgi/content/full/121/13/e266>

BCBSA Medical Policy reference Manual [Electronic Version]. 7.01.86, 2/10/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.111, 10/8/10

Food and Drug Administration (FDA). Pre-market Approval Summary for GORE TAG Thoracic Endoprosthesis. Retrieved on February 11, 2011 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf4/p040043a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040043a.pdf)

Food and Drug Administration (FDA). Pre-market Approval for Talent™ Thoracic Stent Graft System. Retrieved on February 11, 2011 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf7/p070007a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070007a.pdf)

Food and Drug Administration (FDA). Pre-market Approval for Zenith TX2® TAA Endovascular Graft. Retrieved on February 11, 2011 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf7/p070016a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070016a.pdf)

Medical Director review 4/2011

Specialty Matched Consultant Advisory Panel review 6/2011

## Policy Implementation/Update Information

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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 may be considered medically necessary for the treatment of descending **thoracic** aortic aneurysms using devices approved by the U.S. Food and Drug Administration for their approved specifications. References updated. Medical Director review 4/2011. (mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy

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statements (mco)

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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.