



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Endovascular Repair of Thoracic Aortic Aneurysms**

**Effective Date ..... 10/15/2010**  
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## Hyperlink to Related Coverage Policies

Endovascular Repair of Abdominal Aortic Aneurysms

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

## Coverage Policy

**CIGNA covers endovascular repair of aneurysms of the descending thoracic aorta using a U.S. Food and Drug Administration (FDA)-approved endoprosthesis as medically necessary when the device is used according to FDA labeling.**

**CIGNA does not cover placement of an implantable wireless pressure sensor during endovascular aneurysm repair because it is considered experimental, investigational or unproven.**

**CIGNA does not cover monitoring using an implantable wireless pressure sensor following endovascular aneurysm repair because it is considered experimental, investigational or unproven.**

## General Background

An aneurysm is a permanent localized dilation of an artery in which the diameter is at least fifty percent greater than the expected normal artery size. Thoracic aortic aneurysms (TAA) are less common than abdominal aortic aneurysms (AAA), and may involve the ascending aorta, aortic arch, descending aorta or a combination of these segments. TAA may be associated with atherosclerosis, hypertension, trauma, or congenital disorders, including Marfan's Syndrome, Loeys-Dietz syndrome, Turner syndrome, and Ehlers-Danlos Syndrome. TAA are usually asymptomatic and may be diagnosed by chance during evaluation of other medical problems. TAAs typically follow a slow, progressive pattern of growth. Patients with small aneurysms or patients who are not suitable

candidates for surgery or endovascular repair may be treated medically (e.g., antihypertensive therapy, beta blockers, statin therapy). The mortality rate of ruptured TAA is very high, and aneurysm size is the major factor in determining risk of rupture. The risk of rupture, dissection, and death is increased significantly when the aneurysm exceeds six cm in diameter. Repair is generally considered for a TAA diameter of 5.5 centimeters (cm) or more in an asymptomatic patient, or a diameter of less than 5.5 with a growth rate of more than 0.5 cm per year

The conventional treatment for TAA has been open surgery, involving replacement of the affected aortic segment with a synthetic graft, excluding the aneurysm from the arterial circulation. Open surgery, requiring left thoracotomy, may not be tolerated by all patients, especially those who are elderly with severe comorbidities, including chronic obstructive pulmonary disease, hypertension, coronary artery disease, as well as cerebrovascular, renal, and coronary abnormalities associated with arteriosclerosis. Open surgical repair of TAA is associated with significant perioperative complications, including 30-day mortality of 4.89% and paraplegia rates of 4.6%. Stroke and renal failure are also potential complications

Endovascular repair using stent grafts was initially performed for repair of AAAs, and was subsequently introduced as a less invasive alternative for repair of aneurysms of the descending thoracic aorta. With endovascular repair, the stent is delivered through a remote vessel under fluoroscopic guidance, endograft fixation is secured, and a hemostatic seal is formed between the graft and the vessel wall. Endovascular repair of TAA is increasingly employed, with reported advantages of decreased early operative morbidity and mortality. Disadvantages of endovascular repair include the potential for endoleak, embolism, graft migration, and stent fracture, as well as the need for ongoing radiological surveillance. Endoleak, a complication unique to endovascular aneurysm repair, is defined as blood flow within the aneurysm sac but outside the endoluminal graft. Endoleak can lead to aneurysm enlargement and rupture. Long-term screening with computed tomography (CT) and duplex ultrasound is generally performed to monitor for these complications (Abraha, 2009; Hiratzka et al., 2010; Svensson et al., 2007).

#### **U.S. Food and Drug Administration (FDA)**

**Talent™ Thoracic Stent Graft System:** The Talent Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, CA) received U.S. Food and Drug Administration (FDA) approval through the Premarket Approval (PMA) process on June 5, 2008. The device is indicated for endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories
- Non-aneurysmal aortic diameter in the range of 18 - 42mm; and
- Non-aneurysmal aortic proximal and distal neck lengths > 20mm.

The Talent Thoracic Stent Graft is composed of a series of shaped, self-expanding nitinol springs to form a stent. The stent is covered by a polyester woven graft. The graft material is sewn to the stent, and radiopaque markers are sewn to the graft to help visualize and identify the edge of the graft material, stent graft alignment, and the minimum overlap required when multiple stent grafts are used. The Talent Thoracic Stent Graft System is a modular device system that accommodates the use of multiple stent graft sections. Depending on the patient's anatomy, single or multiple stent grafts may be required to achieve coverage and exclude the target lesion. Multiple graft configurations are available to support optimum matching of the device(s) to individual patient anatomies.

**Zenith® TX2® Thoracic TAA Endovascular Graft with the H&LB One-Shot™ Introduction System:** The Zenith TX2® Thoracic TAA Endovascular Graft with the H&LB One-Shot Introduction System (Cook, Inc., Bloomington, IN) received U.S. FDA approval through the Premarket Approval (PMA) process on May 21, 2008. The device is indicated for the endovascular treatment of patients with aneurysm or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with the required introduction systems
- Non-aneurysmal aortic segments (fixation sites) proximal and distal to the aneurysm or ulcer with a length of at least 25 mm, a diameter measured outer wall to outer wall of 24–38 mm

The device is a one-piece or two-piece endovascular graft. The two-piece system consists of a proximal main body component and overlapping distal main body component. The one-piece system may consist of either a one-piece main body component or a proximal main body component (without use of a distal main body component). The stent grafts are constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel stents with braided polyester and monofilament polypropylene sutures.

**GORE TAG Thoracic Endoprosthesis:** The GORE TAG Thoracic Endoprosthesis (W.L. Gore and Associates, Inc., Flagstaff, AZ) received U.S. FDA approval through the PMA process on March 23, 2005. The device was approved for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy, including:

- adequate iliac/femoral access
- aortic inner diameter in the range of 23–37 mm
- $\geq 2$  cm non-aneurysmal aorta proximal and distal to the aneurysm

The device is a flexible, self-expanding endoprosthesis that is constrained on the leading edge of a delivery catheter. The endoprosthesis consists of an expanded polytetrafluoroethylene (ePTFE) tube with a nitinol support structure. The catheter is inserted into the femoral artery, and the endoprosthesis is deployed, excluding the TAA from the circulation.

### Literature Review

Approval of the Medtronic Talent Thoracic Stent Graft was based in part on the VALOR trial (n=195), a prospective non-randomized, multicenter trial to evaluate the safety and efficacy of the Talent stent in the treatment of thoracic aortic disease in patients considered to be candidates for open surgical repair (Fairman et al., for the VALOR Investigators, 2008). The results of endovascular treatment were compared to retrospective data of 189 patients treated with open surgical repair at three centers of excellence. The Talent stent showed statistically superior performance vs. open surgery in acute procedural outcomes ( $p < .001$ ), 30-day major adverse events (41% vs. 84.4%,  $p < .001$ ); perioperative mortality (2% vs. 8%,  $p < .01$ ), and 12-month aneurysm-related mortality (3.1% vs. 11.6%,  $p < .002$ ).

Approval of the Zenith TX2 device was based in part on the STARZ-TX2 Clinical Trial, a non-randomized, controlled multi-center study conducted to evaluate the safety and efficacy of the device in the elective treatment of patients with descending thoracic aortic aneurysm or ulcers (Matsamura et al., for the TX2 Clinical Investigators, 2008). The study compared results of 160 patients treated with the Zenith device to results of 70 patients treated with open repair. The 30-day survival rate for the endovascular group was non-inferior ( $p < .01$ ) to the control group (98.1% vs. 94.3%). Cumulative major morbidity scores at 30 days were significantly lower in the endovascular group compared to the control group ( $1.3 \pm 3.0$  vs.  $2.9 \pm 3.6$ ;  $p < .01$ ). The rate of cardiovascular, pulmonary, and vascular adverse events was also lower in the endovascular group, although there was no significant difference in neurologic events. At 12 months, aneurysm growth was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103 patients), and migration in 2.8% (3/107 patients).

Makaroun et al., for the GORE Tag Investigators (2008), published five year results of a prospective multicenter case series that compared the GORE Tag device (n=140) to surgical controls (n=94) for the treatment of descending thoracic aortic aneurysm (TAA). Results of this trial published at two years served as the phase II trial of the GORE TAG device. At five years, aneurysm related mortality was lower for the TAG patients (2.85) compared to open control patients (11.7%) ( $p = .008$ ). No differences in all-cause mortality were observed; the rate of adverse events was significantly lower in the TAG group (5.9%) than in the control group (78.7%) ( $p = .001$ ). Endoleaks in the TAG group decreased from 8.1% at one month to 4.3% at five years.

### Systematic Reviews

Jonker et al. (2010) conducted a systematic review and meta-analysis of studies published between 1996 and 2009 to evaluate outcomes of open surgical repair (n=81) vs. endovascular repair (n=143) for ruptured descending TAA. The 30-day mortality was 19% for patients treated with endovascular repair, compared to 33% for patients treated with open repair ( $p = .016$ ). The 30-day incidence of myocardial infarction (MI) was 3.5% for those treated with endovascular repair vs. 11.1% in patients treated with open repair ( $p < .05$ ). Rates of stroke and paraplegia were also increased in the surgically treated patients, but did not reach statistical significance.

Additional vascular interventions were performed in 9.1% of endovascular patients vs. 2.3% of surgical patients (p=.169). During a median follow-up of 17 ± 10 months, five additional patients in the endovascular group died of aneurysm-related causes. Endoleak was reported in 11.1% of patients in the endovascular group at some point following repair, and endograft migration was reported in one patient. The authors noted that the cause for concern with endovascular repair remains its durability and the development of endograft-related complications, and that continued surveillance after endoscopic repair and further improvement of the design of endografts is required.

Abraha et al. (2009) conducted a Cochrane systematic review of thoracic stent grafts vs. surgery for thoracic aortic aneurysms (TAA). No randomized controlled trials comparing endovascular repair with conventional open surgical repair were found. The authors stated that reports from non-randomized studies suggest that endovascular repair is technically feasible and may reduce early negative outcomes, including death and paraplegia. Stent devices have late complications that are uncommon in open surgical repair, however, including development of leaks, graft migration, and the need for re-intervention. In addition, patients receiving stents require frequent surveillance with CT scans. Although the available evidence suggests that endovascular repair can be appropriate in selected patients, high quality studies are needed to produce generalizable conclusions.

A systematic review of endovascular repair in the treatment of thoracic aortic disease commissioned by the National Institute of Clinical Excellence (NICE) (United Kingdom) (2005) included 27 case series and two comparative observational studies. Data from the included studies demonstrated achievement of technical success in approximately 93% of cases. The 30-day mortality rate was 5%, and overall mortality rate was 12% across the studies, with a mean follow-up period of 14 months. The most frequent technical complications were endoleak (13%), injury to the access site (6%), and stent fracture (6%). Stroke occurred in 6% and paraplegia in 2% of patients. The authors concluded that the evidence base for assessment of safety and efficacy of endovascular stent graft placement for TAA is poor, consisting primarily of case series that include heterogeneous groups of patients with incomplete outcome data. The review further concluded that the safety of the procedure must be assessed in light of the fact that mortality is very high if patients with thoracic aortic aneurysm are untreated.

#### **National Institute of Clinical Excellence (NICE) (United Kingdom)**

Interventional procedure guidance issued by NICE (2005) states that current evidence on the safety and efficacy of endovascular stent-graft placement in thoracic aortic aneurysms and dissections indicates that it is a suitable alternative to surgery in appropriately selected patients.

#### **Implanted Wireless Pressure Sensor**

The CardioMEMS EndoSure™ Wireless AAA Pressure Measurement System was approved for marketing through the 510(k) process on October 12, 2006 for the measurement of intrasac pressure during endovascular AAA repair and for use as an adjunctive tool in the detection of intraoperative leaks. In a subsequent approval on March 15, 2007, measurement of intrasac pressure during thoracic aortic aneurysm repair was added as an intended use.

According to the 510(k) summary, the sensor is implanted in the aneurysm sac during stent graft deployment and is left in place in the excluded portion of the aneurysm as a permanent implant. The main body of the sensor is composed of fused silica coated in silicone. Nitinol loops extend from and surround the sensor body. The sensor is interrogated using the antenna of the EndoSure Electronics System. Once the signal is acquired, a pressure waveform and numerical pressure data are displayed on the touch-screen, and a printout of the data and waveform is generated.

Published evidence on the use of the CardioMEMS system consists of several diagnostic cohort studies with short-term preliminary results (Hoppe et al., 2008, n=12; Silveira et al., 2008, n=25; Ohki et al., 2007, n=76). The safety and clinical utility of this technology in the intraoperative or long-term monitoring of patients following endovascular aortic aneurysm repair has not been established.

#### **Professional Societies/Organizations**

The 2010 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 Guidelines for the Diagnosis and Management of Patients with Thoracic Aortic Disease include the following recommendations for treatment of aneurysms of the descending thoracic aorta and thoracoabdominal aortic aneurysms:

**Class I**

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 (*Level of Evidence: B*)

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 (*Level of Evidence: B*)

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 Loays-Dietz syndrome is present (*Level of Evidence: C*)

Class I recommendations are defined as follows:

Recommendation that procedure or treatment is useful/effective

- Level of evidence A: Sufficient evidence from multiple randomized trials or meta-analyses
- Level of evidence B: Limited evidence from single randomized trial or nonrandomized studies
- Level of evidence C: Only expert opinion, case studies, or standard of care

**Summary**

The risk of rupture of large or rapidly growing thoracic aortic aneurysms (TAA) is high, and the mortality rate of ruptured TAAs is extremely high. Endovascular TAA repair has demonstrated positive results, with reduced rates of operative mortality and morbidity compared to open repair, and may be a reasonable alternative for patients with aneurysms of the descending thoracic aorta who meet specific anatomic criteria. Additional data is needed to demonstrate the long-term safety, durability and efficacy of endovascular repair, however, and to more clearly define patient selection criteria. Endovascular repair of TAAs should therefore be reserved for patients for whom the risk/benefit ratio favors endovascular repair over open surgical repair.

Implantable wireless pressure sensor monitoring (e.g., CardioMEMS EndoSure™ Wireless AAA Pressure Measurement System) has been proposed as a method to provide intraoperative and long-term monitoring of pressure within the aneurysm in conjunction with endovascular TAA repair. The safety and clinical utility of this technology have not been established.

**Coding/Billing Information**

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT* Codes	Description
33880	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematomas or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33881	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematomas or traumatic disruption); not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33883	Placement of proximal extension prosthesis for endovascular repair of

	descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematomas or traumatic disruption); initial extension
33884	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematomas or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure.)
33886	Placement of distal extension prosthesis (s) delayed after endovascular repair of descending thoracic aorta
33889	Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral
33891	Bypass graft, with other than vein, transcervical retropharyngeal carotid-carotid, performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision
75956	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
75957	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
75958	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption), radiological supervision and interpretation

ICD-9-CM Diagnosis Codes	Description
441.1	Thoracic aneurysm, ruptured
441.2	Thoracic aneurysm without mention of rupture

**Experimental/Investigational/Unproven/Not Covered:**

CPT* Codes	Description
34806	Transcatheter placement of wireless physiologic sensor in aneurysmal sac during endovascular repair, including radiological supervision and interpretation, instrument calibration, and collection of pressure data (List separately in addition to code for primary procedure)
93982	Noninvasive physiologic study of implanted wireless pressure sensor in aneurysmal sac following endovascular repair, complete study including recording, analysis of pressure and waveform tracings, interpretation and report

ICD-9-CM Diagnosis Codes	Description
	All codes

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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## Policy History

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<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	10/15/2008	0416	Endovascular Repair of Thoracic Aortic Aneurysms

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