



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections

**Policy #** 00181

**Original Effective Date:** 10/20/2010

**Current Effective Date:** 11/20/2013

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Endovascular Grafts for Abdominal Aortic Aneurysms are addressed separately in medical policy 00035.*

### When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) to be **eligible for coverage** in the following situations:

- Treatment of descending thoracic aortic aneurysms (TAAs) without dissection (see *Note*);
- Treatment of acute, complicated (organ or limb ischemia or rupture) Type B thoracic aortic dissection.

*Note: 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<sup>®</sup> endoprosthesis is approved by the U.S. FDA for "≥ 2cm non-aneurysmal aorta proximal and distal to the aneurysm and an "aortic inner diameter of 23–37mm." The Talent<sup>™</sup> Thoracic Stent Graft System is approved by the U.S. FDA for "non-aneurysmal aortic proximal and distal neck lengths ≥ 20mm" and "non-aneurysmal aortic diameter in the range of 18–42mm." The Zenith TX2<sup>®</sup> device is approved by the U.S. FDA for non-aneurysmal aortic segments "of at least 25mm in length" and "diameter measured outer wall to outer wall of no greater than 38mm and no less than 24mm."*

Based on review of available data, the Company considers endovascular stent grafts for the treatment of rupture of the descending thoracic aorta to be **eligible for coverage**.

### When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of endovascular stent grafts for the treatment of thoracic aortic arch aneurysms to be **investigational**.\*

### Background/Overview

Thoracic endovascular aneurysm repair (TEVAR) involves the percutaneous placement of a stent graft in the descending thoracic or thoracoabdominal aorta. It is a less invasive alternative to open surgery for the



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treatment of TAAs, dissections, or rupture, and thus has the potential to reduce the morbidity and mortality of open surgery.

### Thoracic Aortic Aneurysms

Aortic aneurysms are arterial dilations that 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.

The indications for the elective surgical repair of aortic aneurysms are based on estimates of the prognosis of the untreated aneurysm balanced against the morbidity and mortality of the intervention. The prognosis of TAA is typically reported in terms of the risk of rupture according to size and location, i.e., the ascending or descending or thoracoabdominal aorta. While several studies have estimated the risk of rupture of untreated aneurysms, these studies have excluded patients who underwent surgical repair; therefore, the true natural history of thoracic aneurysms is unknown. Clouse and colleagues performed a population-based study of TAA diagnosed in Olmstead County, Minn., between the period of 1980 and 1994. A total of 133 patients were identified; the primary clinical endpoints were cumulative rupture risk, rupture risk as a function of aneurysm size, and survival. The cumulative risk of rupture was 20% after 5 years. The 5-year risk of rupture as a function of aneurysm size at recognition was 0% for aneurysms less than 4 cm in diameter, 16% for those 4 to 5.9 cm, and 31% for aneurysms 6 cm or more. Interestingly, 79% of the ruptures occurred in women. Davies and colleagues reported on the yearly rupture or dissection rates in 721 patients with TAA. A total of 304 patients were dissection-free at presentation; their natural history was followed up for rupture, dissection, and death. Patients were excluded from analysis once the operation occurred. Not surprisingly, the authors reported that aneurysm size had a profound impact on outcomes. For example, based on their modeling, a patient with an aneurysm exceeding 6 cm in diameter can expect a yearly rate of rupture or dissection of at least 6.9% and a death rate of 11.8%. In a previous report, the authors suggested surgical intervention of a descending aorta aneurysm if its diameter measured 6.5cm.

Surgical morbidity and mortality are typically subdivided into elective versus emergency repair with a focus on the incidence and risk of spinal cord ischemia, considered one of the most devastating complications, resulting in paraparesis or paraplegia. The operative mortality of surgical repair of aneurysm of the descending and thoracoabdominal aorta is estimated at 6–12% and 10–15%, respectively, while mortality associated with emergent repair is considerably higher. In elective cases, predictors of operative mortality include renal insufficiency, increasing age, symptomatic aneurysm, presence of dissection, and other comorbidities, such as cardiopulmonary or cerebrovascular disease. The risk of paraparesis or paraplegia is estimated at 3–15%. Thoracoabdominal aneurysms, larger aneurysms, presence of dissection, and diabetes are predictors of paraplegia. A number of surgical adjuncts have been explored over the years to reduce the incidence of spinal cord ischemia, including distal aortic perfusion, cerebrospinal fluid drainage,



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hypothermia with circulatory arrest, and evoked potential monitoring. However, the optimal protective strategy is still uncertain.

This significant morbidity and mortality makes definitive patient selection criteria for repair of thoracic aneurysms difficult. Several authors have recommended an individual approach based on balancing the patients' calculated risk of rupture with their anticipated risk of postoperative death or paraplegia. However, in general, surgical repair is considered in patients with adequate physiologic reserve when the thoracic aneurysm measures from 5.5 to 6 cm in diameter or in patients with smaller symptomatic aneurysms.

### Thoracic Aortic Dissection

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 thoracoabdominal aorta.

As noted previously, type A dissections (involving the ascending aorta) are treated surgically. There is more controversy regarding the optimal treatment of type B dissections (i.e., limited to the descending aorta). In general, chronic, stable type B dissections are managed medically, although some surgeons recommended a more aggressive approach for younger patients in otherwise good health. When serious complications arise from a type B dissection, i.e., shock or visceral ischemia, surgical intervention is usually indicated. However, although there is an estimated 50% 1-year survival rate in those treated with an open surgical procedure, it is not clear whether that is any better or worse than those treated medically. The advent of stent grafting, with the potential of reducing the morbidity and mortality of an open surgical procedure, may further expand the number of patients considered for surgical intervention.

### Thoracic Aortic Rupture

Rupture of the thoracic aorta is a life-threatening emergency that is nearly always fatal if untreated. Thoracic artery rupture can result from a number of factors. Aneurysms can rupture due to progressive dilatation and pressure of the aortic wall. Rupture can also occur as a result of traumatic injury to the aorta, such as occurs with blunt chest trauma. Penetrating injuries that involve the aorta can also lead to rupture. Penetrating ulcers can occur in the setting of widespread atherosclerotic disease and lead to aortic rupture. Emergent repair of thoracic artery rupture is indicated in many cases in which there is free bleeding into the mediastinum and/or complete transection of the aortic wall. In some cases of aortic rupture, where the aortic media and adventitia are intact, watchful waiting with delayed surgical intervention can be performed. With the advent of TEVAR, the decision making for intervention may be altered, as there may be a greater tendency to intervene on borderline cases due to the potential for less adverse events with TEVAR.



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### Thoracic Endovascular Aneurysm Repair

Thoracic endovascular aneurysm repair is an alternative to open surgery. Thoracic endovascular aneurysm repair has been proposed for prophylactic treatment of aneurysms that meet criteria for surgical intervention, as well as for patients in need of emergency surgery for rupture or complications related to dissection. The standard open surgery technique for TAA is open operative repair with graft replacement of the diseased segment. This procedure requires lateral thoracotomy, use of cardiopulmonary bypass, long operation times, and is associated with a variety of peri- and postoperative complications, with spinal cord ischemia considered the most devastating.

Thoracic endovascular aneurysm repair is performed through a small groin incision to access the femoral artery, followed by delivery of catheters across the diseased portion of the aorta. A tubular stent graft composed of fabric and metal is then deployed under fluoroscopic guidance. The stent graft is then fixed to the proximal and distal portions of the aorta. Approximately 15% of patients do not have adequate femoral access, and the procedure can be performed by a retroperitoneal approach in these cases.

Potential complications of TEVAR are bleeding, vascular access site complications, spinal cord injury with paraplegia, renal insufficiency, stroke, and cardiopulmonary complications. Some of these complications are similar to those encountered with open repair, such as paraplegia and cardiopulmonary events, and others are unique to TEVAR, such as access site complications.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration

In March 2005, the GORE TAG<sup>®†</sup> Thoracic Endoprosthesis (W.L. Gore and Associates, Inc. Flagstaff, AZ) was approved by the U.S. FDA through the premarket approval (PMA) 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 23–37mm, and equal to or greater than 2cm non-aneurysmal aorta proximal and distal to the aneurysm. In January 2012, the FDA granted an expanded indication for the GORE TAG system to include isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers and/or isolated hematomas, but do not include dissections. Indicated aortic inner diameter is 16-42mm, with  $\geq$  20mm of non-aneurysmal aortic distal and proximal to the lesion.

In May 2008, the Zenith TX2<sup>®‡</sup> TAA Endovascular Graft<sup>™</sup> (Cook Incorporated, Bloomington, IN) 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 24-38mm.

In June 2008, the Talent<sup>™‡</sup> Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, CA) was approved by the FDA through the PMA 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.

In October 2012, the FDA granted approval for the Valiant<sup>™‡</sup> Thoracic Stent Graft with the Captivia<sup>®‡</sup> Delivery System (Medtronic Vascular, Santa Rosa, CA) to include isolated lesions of the thoracic aorta.

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Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers and/or isolated hematomas, but do not include dissections. Indicated aortic diameter is 18-42mm for aneurysms and penetrating ulcers, and 18-44mm for blunt traumatic injuries.

Other devices are under development, and in some situations, physicians have adapted other commercially available stent grafts for use in the thoracic aorta.

Centers for Medicare and Medicaid Services (CMS)

No national coverage determination.

### **Rationale/Source**

Controlled trials of specific patient groups treated with specific procedures are required to determine if endovascular approaches are associated with equivalent or improved outcomes compared to surgical repair. For patients who are candidates for surgery, open surgical resection of the aneurysm with graft replacement is considered the gold standard for treatment of aneurysms or dissections. Some patients who would not be considered candidates for surgical therapy due to unacceptable risks might be considered candidates for an endovascular graft. In this situation, the outcomes of endovascular grafting should be compared to optimal medical management. Comparative mortality rates are of high concern, as are the rates of serious complications such as the incidence of spinal cord ischemia.

Randomization to treatment groups is also very important in this area. This is due to the numerous patient factors (i.e., age, co-morbidities, location, size of the aneurysm, presence or absence of dissection) and procedure variables involved in surgical repair that are potential confounders of outcome. Selection for either open or endovascular repair involves a complex set of patient and anatomical considerations. As a result, studies are highly prone to selection bias if there is not randomized assignment.

### **Aneurysms of the Descending Thoracic Aorta**

There are no randomized controlled trials (RCTs) of endovascular repair versus open surgery for thoracic aneurysms. The best evidence consists of non-randomized comparative studies and systematic reviews of these studies. The following review includes representative prospective, non-randomized studies and selected systematic reviews.

### **Systematic Reviews**

A systematic review of the evidence for endovascular repair of thoracic aneurysms was published by the Cochrane Peripheral Vascular Diseases Group in January 2009 and was based on the literature to October 2008. No RCTs comparing endovascular repair to open surgical interventions for thoracic aneurysms were found in the medical literature. Reports from non-randomized studies suggest that endovascular repair is technically feasible and may reduce early negative outcomes, including death and paraplegia. However, endovascular repair is associated with late complications not often seen in open surgery, such as the development of leaks, graft migration, and need for re-intervention. Patients receiving endovascular grafts also more require frequent surveillance with computed tomography (CT) scans and have increased radiation exposure.



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## **Non-randomized Comparative Studies**

### TAG 99-01 Study

The TAG 99-01 study was a controlled trial of patients with aneurysms of the descending thoracic aorta treated with either surgical repair (n = 94; 50 historical, and 44 concurrent) or stent grafting (n = 140) at 17 sites in the United States. Patients for both the graft group and the control group were selected using the same inclusion and exclusion criteria. After fractures in the wire frame of the TAG endoprosthesis were discovered in TAG 99-01, 51 patients underwent stent grafting with a modified TAG endoprosthesis at 11 sites in the subsequent TAG 03-03 study. The primary outcomes assessed in both TAG 99-01 and TAG 03-03 were the number of patients who had 1 or more major adverse events and the number of patients who did not experience device-related events 12 months' post-device deployment. The number of patients in the TAG 99-01 device group who experienced equal to or greater than 1 major adverse event (42%) was significantly lower ( $p < 0.001$ ) than the surgical repair control group (77%) at 1-year follow-up. Major adverse events included major bleeding, neurologic; pulmonary; renal function; and vascular complications. In the TAG 99-01 device group, 4 of 140 patients (3%) experienced paraplegia or paraparesis versus 13 of 94 patients (14%) in the control group.

In the 12-month follow-up of TAG 99-01, 8 patients (3%) had 1 or more major adverse device-related events, while the 12- to 24-month follow-up in this group only noted 1 major adverse device-related event. No major adverse device-related events occurred in the 30-day follow-up of the TAG 03-03 group. Information on 142 patients from the TAG 99-01 trial was published by Makaroun and colleagues; however, the authors did not report on comparative data with the surgical control group, citing regulatory requirements pending FDA review. The Makaroun et al. report of the TAG 99-01 study reported favorable aneurysm-related (97%) and overall survival (75%) rates and concluded that the GORE TAG device was a safe alternative treatment for descending TAAs.

These same authors have also reported 5-year outcomes of the TAG 99-01 trial. In this follow-up of 140 endograft patients and 96 non-contemporaneous controls, the authors concluded that endovascular treatment was superior to surgical repair at 5 years in anatomically suitable patients. At 5 years, aneurysm-related mortality was lower for TAG patients at 2.8% compared with open controls at 11.7% ( $p = 0.008$ ). No differences in all-cause mortality were noted, with 68% of TAG patients and 67% of open controls surviving to 5 years. Endoleaks in the TAG group decreased from 8.1% at 1 month to 4.3% at 5 years. Five TAG patients have undergone major aneurysm-related re-interventions at 5 years (3.6%). For this study, significant sac size change was defined as 5 mm or greater increase or decrease from the 1-month baseline measurement. Migration was defined as 10 mm or more cranial or caudal movement of the device inside the aorta. Compared with the 1-month baseline, sac size at 60 months decreased in 50% and increased in 19% of TAG patients. At 5 years, there have been no ruptures, 1 migration, no collapse, and 20 instances of fracture in 19 patients, all before the revision of the TAG graft. They also noted that although sac enlargement was concerning, a modified device may be helping to resolve this issue.

### VALOR Study

The Evaluation of the Safety and Effectiveness of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) study was a nonrandomized study conducted at 38 sites within the United States. The VALOR trial enrolled patients who were candidates for

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open surgical repair and compared 195 TAA patients (aged: 70.2+/-11.1 years; male 59%) to 189 retrospective open surgical repair controls (aged: 69.6+/-9.1 years; male: 52.4%). Patients in the Talent endovascular graft group had lower TAA size and were less likely to have a previous aortic aneurysm (37/195 compared to 70/189 in the surgery group). Talent subjects were also less likely to have comorbid conditions including angina (pooled relative risk [PRR]: 1.6; 95% confidence interval [CI]: 1.0, 2.6), coronary artery disease (PRR: 1.2; 95% CI: 1.0, 1.5) and previous myocardial infarction (MI) (PRR: 1.3; 95% CI: 1.0, 1.6). Thirty-day (Talent group: 4/195 vs. surgery group: 15/189;  $p < 0.1$ ) and 12-month mortality (Talent group 31/192 vs. surgery group: 39/189;  $p < 0.01$ ) was lower in the endovascular graft group compared to open surgery. Fewer endovascular graft patients required blood transfusions (Talent: 22% vs. 93%). Endovascular graft patients had a shorter intensive care unit (Talent: 2 +/-5.5 days vs. surgery: 8+/-8.5 days) and overall hospital stay (Talent: 6+/-11.5 days vs. 17+/-15 days).

### Goodney et al.

These authors used Medicare claims data from 1998-2007 to compare TEVAR with open surgery in patients with aneurysms of the descending aorta. This study included both intact and ruptured aneurysms. A total of 13,998 patients with intact aneurysms were identified; 11,565 were treated with open surgery and 2,433 with TEVAR. There were baseline differences between the 2 groups, with the TEVAR group being older and more likely to have a variety of medical comorbidities. The authors performed 2 comparisons, an unadjusted comparison of outcomes in all patients and a propensity-matched comparison in a subset of 1,100 patients.

Thirty-day mortality was slightly lower among TEVAR patients compared to open surgery, but this difference did not reach statistical significance (6.1% vs. 7.1%,  $p = 0.07$ ). In the propensity-matched comparison, there was no difference in 30-day mortality between the TEVAR and open surgery group (4.5% vs. 4.2%,  $p = 0.78$ ). Long-term survival was reported by Cox proportional hazards analysis. At 5 years, survival in the TEVAR group was lower than for the open surgery group (62% vs. 72%,  $p = 0.001$ ). In the propensity-matched comparison, the TEVAR group also had lower overall survival at 5 years compared to the open surgery group (73% vs. 81%,  $p = 0.007$ ).

### Matsumara et al.

The Zenith TX2 device also received PMA from the FDA based on results of Matsumara et al. The study was a prospective cohort study that compared 160 TEVAR patients (aged: 72+/-9.6 years; male: 72%) to 70 open surgery patients (aged: 68+/-12 years; male 60%). The study arms were comparable in previous history of cardiovascular and other vascular disease. The TEVAR patients had a lower American Society of Anesthesiologist classification ( $p < 0.01$ ) and higher Society of Vascular Surgery/International Society of Cardiovascular Surgery risk score ( $p = 0.03$ ).

The 30-day survival rate for the endovascular group was non-inferior ( $p < 0.01$ ) to the control group (98.1% vs. 94.3%, respectively). The 30-day severe morbidity composite index (cumulative mean number of events per patient) was significantly lower in the endovascular group compared to the control group ( $0.2 \pm 0.7$  vs.  $0.7 \pm 1.2$ ;  $p < 0.01$ ). 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). At 12 months,



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### Orandi et al.

Orandi et al. published a comparative analysis of 1,030 patients undergoing open surgery and 267 undergoing endovascular repair using the Nationwide Inpatient Sample database. In-hospital mortality was similar between open and endovascular patients (adjusted odds ratio [OR]: 1.2, 95% CI: 0.73-2.12). Patients undergoing endovascular repair had fewer cardiac, respiratory, and hemorrhagic complications and a decreased length of hospital stay compared to open surgery patients. Dick et al. compared clinical and quality-of-life outcomes in 52 patients undergoing endovascular repair with 70 patients undergoing open surgical repair. Perioperative mortality rates did not differ between groups (8% vs. 9%, respectively;  $p = 0.25$ ). The mean overall quality-of-life score was 93 for the open surgery group compared with 83 for the endovascular group ( $p = 0.66$ ). There were no significant differences between groups on anxiety, depression, or other quality-of-life sub-measures.

### Conclusions

There are no RCTs of TEVAR versus open surgery for elective repair of TAAs, with the best evidence on this question consisting of non-randomized, comparative studies. The main limitation of these studies is non-comparability of groups, with group differences demonstrated between endovascular and surgical patients in nearly all cases. In some instances, TEVAR patients appear to be less severely ill than open surgery patients, but in other instances, the TEVAR population appears to be more severely ill. These group differences preclude definitive conclusions about the comparative efficacy of endovascular versus open surgery for repair of thoracic aneurysms.

The results of these studies are consistent in showing equivalent or reduced short-term mortality and fewer early complications for TEVAR. The consistency of this finding across populations with different characteristics lends support to the conclusion that TEVAR is a safer procedure in the short term. The likely short-term benefits of TEVAR are mitigated by longer-term outcomes that are less favorable for TEVAR. Longer-term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery, and some studies report that long-term survival is better following open surgery. Thoracic endovascular aneurysm repair patients have a higher rate of long-term complications, primarily from endoleaks, and a higher re-intervention rate. Thoracic endovascular aneurysm repair patients also require closer monitoring after intervention, with more frequent imaging studies.

### **Dissection of the Descending Aorta (Type B Dissection)**

One RCT, the Investigation of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial has been completed for patients with chronic, stable dissections. There are no RCTs for treatment of acute, complicated type B dissections, which is the group for which endovascular repair is often targeted.

### **Systematic Reviews**

A systematic review by Zhang et al identified 5 non-randomized, controlled trials of endovascular repair versus open surgery for acute type-B dissection, reporting on a total of 318 patients. The quality of the evidence was rated low for the outcome of mortality and very low for other outcomes, according to the



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GRADE evaluation. Combined results showed a significant reduction for the TEVAR group on short-term mortality (OR: 0.19, 95% CI: 0.09-0.39), but no difference on long-term mortality (OR: 1.40, 95% CI: 0.24-8.18). There were also no differences on adverse event outcomes, including spinal cord injury, renal failure, stroke, MI, respiratory failure, bowel ischemia, and lower limb ischemia.

Thrumurthy et al. performed a systematic review of endovascular repair for chronic type B dissections, defined as dissections that present with symptoms for greater than 14 days. There were 17 publications included in this review, consisting of one RCT (the INSTEAD trial, discussed below) and 16 single-arm series. Of the 16 single-arm series, 2 were prospective and 14 were retrospective. At a median of 24 months follow-up, mortality was 9.2% for patients treated with TEVAR, with a range of 0-41% across studies. A total of 8.1% of patients had endoleaks at this follow-up, and there was an increasing rate of endoleaks with longer follow-up times. Delayed aortic rupture occurred in 3.0% of patients. Freedom from reintervention occurred in a range of 40-100% at 24 months' follow-up.

### Randomized, Controlled Trials

#### Investigation of Stent Grafts in Patients with type B Aortic Dissection Trial

One RCT, the INSTEAD trial has been completed. This trial compared endovascular stenting with medical management for stable thoracic aortic dissections. Stable, or uncomplicated type B dissections differ from acute lesions in that there is no evidence of ischemia or extension over the time of observation that would necessitate emergency surgery. Patients were randomly assigned to elective stent-graft placement in addition to optimal medical management (n = 72) or to optimal medical management alone (n = 68) to maintain arterial pressure below 120/80mm/Hg. The primary endpoint of all-cause mortality at 1 year did not reach statistical significance between the 2 groups: cumulative survival was 91.3%  $\pm$  2.1% in the endovascular group and 97.0%  $\pm$  3.4% in the medical-only group (p = 0.16). In addition, aorta-related mortality did not differ (5.7% and 3.0%, respectively; p = 0.42). There were 2 cases of ischemic spinal cord injury with stent-grafting and one in the medical group. Seven patients (10.6%) in the medical group did cross over to the stent-graft group due to deterioration in condition, one patient from each group required open surgical intervention within the 12-month study period. An additional stent-graft for false-lumen expansion was required in 6 patients. A secondary measure of aortic remodeling did occur more frequently in the endovascular-repair group (91.3% vs. 19.4%, respectively; p < 0.001), but the clinical significance of this is as yet unknown. Three adverse neurologic events occurred in the endovascular group compared to one in the medical-only arm. The authors conclude that elective stent-graft placement does not improve survival at 1 year and call for larger studies with extended follow-up.

### Non-randomized, Comparative Trials

Jia et al. performed a prospective, multicenter, nonrandomized comparative study of TEVAR versus optimal medical therapy (OMT) for chronic type B thoracic aortic dissections. A total of 208 patients were treated with TEVAR and 95 patients were treated with OMT. In the TEVAR group, there were no periprocedural deaths and serious complications (retrograde type A dissection; brachial artery pseudoaneurysm; paraplegia; MI) occurred in 12 patients (5.8%). Estimated survival at 2 and 4 years was 87.5% and 82.7% with TEVAR, compared to 77.5% and 69.1% with OMT, both respectively, but this difference in survival did not reach statistical significance (p = 0.068). The estimated freedom from aorta-related death at 2 and 4



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years was 91.6% and 88.1% for the TEVAR group, compared to 82.8% and 73.8% with OMT, both respectively, a difference which was statistically significant ( $p = 0.039$ ).

In a retrospective review of the University of Pennsylvania's database of acute type B aortic dissection, Zeeshan and colleagues compared 45 patients who underwent TEVAR to 32 patients who had open surgical repair ( $n = 20$ ) or medical management ( $n = 12$ ). Two TEVAR patients had died within 30 days or within hospitalization compared to 8 open surgery and 4 medical patients (4% vs. 40% vs. 33%, respectively;  $p = 0.006$ ). While not controlled in this study, TEVAR appears to be an option for patients with this catastrophic presentation. One-year survival was 82% for the TEVAR group.

One retrospective study compared outcomes of endovascular repair with medical therapy for acute type B aortic dissections. Of 88 patients presenting with acute dissection over a 12-year period, 50 were treated medically and 38 were treated with endovascular repair. Overall mortality was reported for a mean follow-up of 33–36 months and did not differ between the medical therapy and endovascular groups (24% vs. 23.7%, respectively;  $p =$  not significant).

### Single-arm Studies

A number of single-arm series have also been performed, and some of these report long-term results for use of TEVAR in complicated type B aortic dissection.

White and colleagues analyzed 1-year outcome after TEVAR in patients with complicated type B aortic dissection (cTBAoD) who had rupture or malperfusion and symptom onset 14 days or less (acute), 15 to 30 days (subacute), and 31 to 90 days (chronic) until required intervention. Their report focused on the acute cohort. Clinical data were systematically collected from 5 physician-sponsored investigational device exemption (IDE) clinical trials between 2000 and 2008. Adverse events were reported early (30 days or less) and late ( $> 30$  days). Major adverse events included death, stroke, MI, renal failure, respiratory failure, paralysis, and bowel ischemia. In this study, there were 99 cTBAoD patients: 85 were acute, 11 were subacute, and 3 were chronic. Among the acute patients, 31.8% had rupture and 71.8% had malperfusion, including 55.7% lower extremity, 36.1% renal, 19.7% visceral, 8.2% other, and 3.3% spinal cord (patients may have more than one source). Rupture and malperfusion were both reported for 3 acute patients. Early major adverse events occurred in 37.6% of patients, including death (10.6%), stroke (9.4%), renal failure (9.4%), and paralysis (9.4%); late adverse events included vascular (15.8%), cardiac (10.5%), gastrointestinal (6.6%), and hemorrhage (5.3%). The point-estimate mortality rate was 10.8 (95% CI: 4.1–17.5) at 30 days and 29.4 (95% CI: 18.4–40.4) at 1 year, when 34 patients remained at risk. The authors concluded that emergency TEVAR for patients with cTBAoD (malperfusion or rupture) provides acceptable mortality and morbidity results out to 1 year.

Steuer and colleagues published a retrospective, single-center, consecutive case series from Europe. In this study, during the period 1999–2009, TEVAR was carried out in 50 patients with non-traumatic acute complicated type B dissection and in another 10 patients with acute complications, including rupture, end-organ ischemia, and acute dilatation during the primary hospitalization but more than 14 days after onset of symptoms. In total, 60 patients were included. Within 30 days, 2 (3%) deaths, 1 (2%) paraplegia, and 3 (5%) strokes were observed. Five-year survival was 87% and freedom from re-intervention at 5 years was



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65%. The authors concluded that in patients with acute complicated type B aortic dissection, TEVAR can be performed with excellent early and long-term survival.

## Conclusions

For patients with chronic, stable dissections of the thoracic aorta, one RCT reports that outcomes of TEVAR are not superior to medical management. Single-arm series report relatively high success rates and favorable long-term results compared to historical controls undergoing open surgery.

For patients with acute, complicated type B dissections, there is limited evidence from small, nonrandomized comparative trials, one of which reports a significant early survival advantage for patients treated with TEVAR. This evidence is limited by the small number of studies and non-comparability of treatment groups in the comparative studies. Single-arm series report relatively high success rates and short-term survival that is possibly better than expected with open surgery.

## Rupture of the Descending Aorta

### **Systematic Reviews**

In 2010, Jonker and colleagues published a systematic review and meta-analysis of studies published between 1996 and 2009 to evaluate outcomes of open surgical repair (n = 81) versus 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 = 0.016). The 30-day incidence of MI was 3.5% for those treated with endovascular repair versus 11.1% in patients treated with open repair (p < 0.05). 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 versus 2.3% of surgical patients (p = 0.169). Regarding safety, during a median follow-up of 17 ± 10 months, 5 additional patients in the endovascular group died of aneurysm-related causes, endoleak was reported in 11.1% of patients, and endograft migration was reported in 1 patient. The authors noted that the durability and development of endovascular-related complications remain concerns and that further surveillance of the endografts is required. These data need to be interpreted with caution given the non-random treatment assignment.

Lee et al. summarized data on use of TEVAR for repair of traumatic thoracic aortic injuries to aid development of practice guidelines. The systematic review included 7,768 patients from 139 studies. This review found the mortality rate was significantly lower in patients who underwent endovascular repair, followed by open repair, and nonoperative management (9%, 19%, and 46%, respectively, p < 0.01). Based on the overall very low quality of evidence, the committee suggests that endovascular repair of thoracic aortic transection is associated with better survival and decreased risk of spinal cord ischemia, renal injury, graft, and systemic infections, compared with open repair or nonoperative management. In addition to the low quality of the evidence, the authors also note that these conclusions should be tempered by the lack of suitable (anatomic fit) devices, which can lead to severe complications, and to the lack of follow-up data.



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## **Non-randomized, Comparative Studies**

### Azizzadeh et al.

This non-randomized study compared outcomes of TEVAR and open surgery using prospectively collected data in 106 consecutive patients between 2002 and 2010 at one institution. This time interval covered the period of adoption for TEVAR at this institution, in which the proportion of patients treated with TEVAR increased from 0% to 100%. As a result, the number of procedures done in each group over time varied; 56 patients underwent open surgery and 50 underwent TEVAR. Primary outcomes were in-hospital death and complications. Death occurred in 5/56 (8.9%) patients undergoing open surgery, compared to 2/50 (4.0%) patients undergoing TEVAR. The overall likelihood of complications, including death, was significantly lower in the TEVAR group (OR 0.33, 95% CI 0.11-0.97). Also, the number of patients with at least one complication was greater in the open surgery group compared to TEVAR (69.6% vs. 48%).

### Canaud et al.

This study compared outcomes of endovascular and open surgical repair in 75 patients with acute traumatic rupture of the thoracic aorta at one tertiary care center. Open surgery was performed on 35 patients during the time period of 1990-2000, and endovascular repair was performed on 40 patients between 2001 and 2010. Early mortality was lower in the endovascular group compared to open surgery (2.5% vs. 11.4%), but this difference did not reach statistical significance. Serious adverse events occurred in 20% of patients in the endovascular group compared to 14.2% in the open surgery group, which was also not a significant difference. There were no cases of paraplegia or stroke in either group.

### Goodney et al.

These authors used Medicare claims data from 1998-2007 to compare TEVAR with open surgery in patients with aneurysms of the descending aorta. This study included both intact and ruptured aneurysms. A total of 1,307 patients with ruptured aneurysms were identified, 1,008 were treated with open surgery and 299 with TEVAR. There were baseline differences between the 2 groups, with the TEVAR group being older and more likely to have a variety of medical comorbidities. Thirty-day mortality was significantly lower among TEVAR patients compared to open surgery (28.4% vs. 45.6%,  $p = 0.0001$ ). Long-term survival was reported by Cox proportional hazards analysis. At 5 years, survival was low in both groups with no significant difference between the TEVAR and open surgery groups (23% vs. 26%,  $p = 0.37$ ).

### Gopaldas et al.

Gopaldas et al. used the U.S. Nationwide Inpatient Sample database to identify patients who underwent procedures to repair a thoracic artery rupture. A total of 923 patients were identified between the period of 2006-2008, 364 (39.4%) who underwent TEVAR and 559 (60.6%) who underwent open repair. Patients undergoing TEVAR were older and had a significantly higher burden of comorbidities compared to patients undergoing open repair. Overall mortality was 23.4% for TEVAR and 28.6% for open repair, which was not significantly different. There were also no differences in complication rates. Thoracic endovascular aneurysm repair patients were more likely to have routine discharge from the hospital to home compared to open surgery patients (OR: 3.3,  $p < 0.001$ ).



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### U.S. Food and Drug Administration Approval Studies (Single-arm)

Data from two uncontrolled clinical series of patients with isolated thoracic artery lesions was reviewed by the FDA as part of the expanded approval for thoracic endografts in 2012. The TAG 08-02 study used the GORE TAG endograft to treat 51 patients with aortic transection due to blunt aortic injury. All 51 patients had successful implantation of the CORE TAG endograft, although 6 patients (11.8%) required deployment of two stent grafts for adequate coverage. There were 4 deaths within 30 days of treatment (7.8%, 95% CI 3.1-18.5%). Serious adverse events were reported in 39.2% of subjects at 30 days, with the most common events being pleural effusion (5.9%) respiratory failure (5.9%). The primary effectiveness outcome was the number of patients with major device-related events in the first 30 days requiring reintervention. There were no patients who had such an event requiring reintervention. Two patients were identified with type II endoleaks, but neither patient required reintervention.

A similar study (RESCUE) was submitted to the FDA using the Valiant Thoracic stent graft in 50 patients with blunt aortic trauma. All patients had successful deployment of the stent, with 2 patients requiring 2 devices. There were 4 deaths within 30 days of the procedure for a perioperative mortality of 8.0%. Serious adverse events occurred in 12.0% of patients, the majority of these were procedure-related events such as femoral artery dissection, localized hematoma, and/or hemothorax. There were 3 patients who required left subclavian artery revascularization to treat arm ischemia.

### Conclusions

U.S. Food and Drug Administration approval was granted for endovascular stent graft treatment of thoracic artery ruptures in 2012. The evidence on TEVAR for treatment of thoracic artery rupture consists of single-arm series and nonrandomized comparative studies. There are no randomized, controlled trials, but RCTs are likely difficult to complete for this indication because of the emergent nature. The available evidence suggests that early mortality and complications are less with TEVAR compared with open surgery, but these data are limited by non-comparability of groups. The longer-term outcomes are uncertain, with no discernible differences between TEVAR and open surgery.

### **Mixed populations**

In 2005, the National Institute of Clinical Excellence (NICE) conducted a systematic review of 27 case series and 2 comparative observational studies of endovascular repair in the treatment of thoracic aortic disease. Data from the included studies demonstrated technical success in approximately 93% of cases. The short-term (30-day) mortality rate was 5% (range 0-14%), and with a mean follow-up period of 14 months, overall mortality rate was 12% (range 3-24%) across studies. The most frequent technical complications were endoleaks (13%), injury to the access site (6%), and stent fracture (6%). Stroke occurred in 6% and paraplegia in 2% of patients. The evidence base primarily consists of case series that include heterogeneous groups of patients with incomplete outcome data. However, the review concluded that the safety of the procedure must be weighed against the fact that mortality is very high if patients with TAA are untreated and that endovascular stent placement is a suitable alternative to open surgery in appropriately selected patients with aneurysm or dissection.

In 2009, Cambria and colleagues reported on 59 patients who received TEVAR for emergent repair of thoracic aorta pathology due to acute complicated type B dissection, traumatic aortic tear, and ruptured



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degenerative aneurysm. The authors' own literature review prospectively postulated a combined mortality/paraplegia rate of 12.6% for TEVAR, compared to 29.6% for open surgery for each of the 3 diagnostic conditions, or arms, of the study. Based on pre-study power analysis, it was estimated that 52 test subjects would be required overall to detect a difference of 17% in the composite outcome; 20 subjects were enrolled in each arm, subject to anatomic considerations; at the time of presentation, the final number of subjects drafted was 59 due to a solitary patient reclassification. The combined 30-day mortality/paraplegia endpoint was observed in 13.6% of study participants (7 deaths and 1 paraplegia), significantly lower than the literature-based rate for open surgery (29.6%) previously stated ( $p = 0.008$ ). Not surprisingly, 30-day complications in addition to the composite endpoint were high: 48 (81%) patients experienced at least one major complication. Of these, 11 (18.6%) were attributable to device failure or complication. During mean follow-up time of  $409 \pm 309$  days, an additional 12 patients had died, 1 patient was converted to open surgery, and 2 patients had major, device-related events. For the entire study group, survival at 1 year was 66% ( $n = 40$ ). Regression analysis revealed that age and concurrent chronic obstructive pulmonary disease were predictive of death at 1 year.

Naughton et al. reported on 100 patients with "acute thoracic aortic catastrophies" treated with either TEVAR ( $n = 76$ ) or open surgery ( $n = 24$ ). Conditions included ruptured aneurysms ( $n = 41$ ), traumatic transection ( $n = 27$ ), complicated acute type B dissections ( $n = 20$ ), penetrating ulcers ( $n = 4$ ), intramural hematoma ( $n = 3$ ), penetrating injury ( $n = 3$ ), and embolizing lesions ( $n = 2$ ). Patients in the open surgery group were older and had more prior episodes of aortic surgery. Overall mortality at 30 days was lower for the TEVAR group compared to open surgery (8% vs. 29%,  $p = 0.007$ ). Respiratory complications (16% vs. 48%,  $p < 0.05$ ) were also lower in the TEVAR group. There were no significant differences in postoperative adverse events or mean length of stay.

### Summary

Endovascular stenting is an alternative treatment to surgical or medical therapy for TAAs, acute and chronic dissections, and traumatic aortic tears. For patients with stable aneurysms, there are no randomized trials of stenting versus open surgery. The non-randomized comparative trials available are consistent in reporting reduced short-term morbidity and mortality, but are prone to selection bias and other methodologic limitations. Multiple studies suggest that for elective repair of descending TAAs, stenting is associated with lower short-term mortality and lower complication rates, compared to open surgery. In addition, there was strong clinical vetting support for the use of TEVAR in descending TAAs. Thus, use of endovascular stents may be considered medically necessary for aneurysms of the descending thoracic aorta.

The data for complex situations are more limited. Short- and intermediate-term results from a few non-randomized comparative studies and a number of case series suggest a benefit for TEVAR in complicated (organ or limb ischemia or rupture) type B dissection. There was strong clinical support for the use of TEVAR for this indication. Thus, this use of TEVAR is considered medically necessary. For uncomplicated descending (type B) aortic dissections, the evidence available from one randomized trial does not suggest that stent grafts have superior outcomes compared to medical therapy. Thus, the impact on net health outcome is not known, and the use of endovascular stent grafts in uncomplicated thoracic aortic dissections is considered investigational.

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For traumatic thoracic aortic injury and aortic rupture, nonrandomized comparative data suggest a benefit for TEVAR in reducing peri-procedural morbidity and mortality. The FDA granted approval for endovascular treatment of thoracic aortic ruptures in 2012, and specialty society recommendations include endovascular stent grafts as a treatment option for acute thoracic aortic rupture. In addition, it is expected that RCTs will be difficult to perform for this indication due to the emergent nature. Therefore, based on the available evidence, FDA approval of stent grafts for rupture, and support in specialty society guidelines, stent grafting for acute rupture of the thoracic descending aorta may be considered medically necessary.

### Ongoing Trials

The ADSORB trial is an RCT of stent grafting versus medical therapy for acute dissections of the thoracic aorta. Enrollment is planned for 61 patients who will be followed for 36 months. Primary endpoints will be aneurysmal rupture, aortic enlargement, and thrombosis of the false lumen.

A search of online site [ClinicalTrials.gov](http://ClinicalTrials.gov) using the terms thoracic and endovascular returned 28 active trials of endovascular repair of thoracic artery disorders. The majority of these are single-arm series of different endovascular techniques in various clinical populations. There were no additional randomized, controlled trials, and there were several non-randomized comparative trials, described further below.

NCT01852773. Thoracic Endovascular Repair versus Open Surgery for Blunt Injury. This is a prospective observational trial comparing outcomes of endovascular repair with open surgery for patients with trauma and blunt aortic injury. The main outcomes are short-term mortality and short- and long-term complications. Planned enrollment is for 1,300 patients with an estimated completion date of November 2018.

The STARZ-TX2 Clinical Study: Study of Thoracic Aortic Aneurysm Repair With the Zenith TX2 Endovascular Graft (NCT00111176) is a non-randomized, comparative trial of TEVAR versus open surgical repair for patients with thoracic aneurysms who are eligible for both procedures. Planned enrollment is for 205 patients with an estimated completion date of May 2013.

Trials NCT00998491 (A Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft in Patients With Thoracic Aortic Pathologies (RELAY)) and NCT00435942 (Phase II Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft) are Phase II studies to evaluate the safety and efficacy of the Relay Stent Graft in patients with descending thoracic aneurysms. NCT00998491 has a planned enrollment of 180 patients, with an estimated completion date in 2015. NCT00435942 has a planned enrollment of 120 patients and an estimated completion date in 2015.

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11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Eligible for coverage statements reformatted to clarify the intent that use is for specific types of aneurysms without dissection, for complicated Type B dissections and for traumatic aortic injury (when specific conditions are met). Added a <i>Note</i> to the coverage section for clarification.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. Eligible for coverage indication added for acute rupture of the thoracic aorta.

Next Scheduled Review Date: 11/2014

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. reference to federal regulations.

\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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## Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections

Policy # 00181

Original Effective Date: 10/20/2010

Current Effective Date: 11/20/2013

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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