# Endovascular Stent Grafts for Disorders of the Thoracic Aorta

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*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* below);
- Treatment of acute, complicated (organ or limb ischemia or rupture) Type B thoracic aortic dissection.

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 lesions that do not meet the above criteria, including but not limited to thoracic aortic arch aneurysms to be **investigational.***

## Policy Guidelines

Endograft placement relies on nonaneurysmal 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 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 FDA for "non-aneurysmal aortic proximal and distal neck lengths ≥20 mm" and a "non-aneurysmal aortic diameter in the range of 18–42 mm." The Zenith TX2 Endograft placement relies on nonaneurysmal 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 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 FDA for "non-aneurysmal aortic proximal and distal neck lengths ≥20 mm" and a "non-aneurysmal aortic diameter in the range of 18–42 mm." The Zenith TX2®‡ device is approved by FDA for nonaneurysmal aortic segments "of at least 25 mm in length" and a "diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm."

## Background/Overview

### THORACIC AORTIC ANEURYSMS

Aortic aneurysms are arterial dilations associated with age, atherosclerosis, and hypertension, as well as some congenital connective tissue disorders. The likelihood of significant sequelae from aortic aneurysm depends on the 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 that impinge on the true lumen of the aorta or occlude branching vessels are a surgical emergency.

#### Treatment

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 thoracic aortic aneurysm (TAA) is typically reported regarding the risk of rupture according to size and location (ie, 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 et al (1998) performed a population-based study of TAA diagnosed in Minnesota, between 1980 and 1994. A total of 133 patients were identified; the primary clinical end points 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 et al (2002) 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 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 could expect a yearly rate of rupture or dissection of at least 6.9% and a death rate of 11.8%. In a previous report, these same authors suggested surgical intervention of a descending aorta aneurysm if its diameter measured 6.5 cm.

Surgical mortality and morbidity are typically subdivided into emergency and elective repair, with a focus on the incidence and risk of spinal cord ischemia, considered 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% to 12% and 10% to 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, the presence of dissection, and other comorbidities (eg, cardiopulmonary or cerebrovascular disease). The risk of paraparesis or paraplegia is estimated at 3% to 15%. Thoracoabdominal aneurysms, larger aneurysms, the presence of dissection, and diabetes are predictors of paraplegia. A number of surgical adjuncts have been explored to reduce the incidence of spinal cord ischemia, including distal aortic perfusion, cerebrospinal fluid drainage, hypothermia with circulatory arrest, and evoked potential monitoring. However, the optimal protective strategy is still uncertain.

This significant mortality and morbidity risks make 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 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. 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.

**Treatment**
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. 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, type A dissections (involving the ascending aorta) are treated surgically. There is more controversy regarding the optimal treatment of type B dissections (ie, limited to the descending aorta). In general, chronic, stable type B dissections are managed medically, although some surgeons have recommended a more aggressive approach for younger patients in otherwise good health. When serious complications arise from a type B dissection (ie, shock or visceral ischemia), surgical intervention is usually indicated. Although there is an estimated 50% one-year survival rate in those treated with an open surgical procedure, it is not clear whether that rate is any better or worse for those treated medically. The advent of stent grafting, with the potential of reducing the mortality and 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 result from 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 widespread atherosclerotic disease and lead to aortic rupture.

**Treatment**
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 is a treatment option. With the advent of thoracic endovascular aneurysm repair (TEVAR), the decision making for intervention may be altered, because there may be a greater tendency to intervene in borderline cases due to the potential for fewer adverse events with TEVAR.

***Thoracic Endovascular Aneurysm Repair***
TEVAR is an alternative to open surgery. TEVAR 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 a lateral thoracotomy, use of cardiopulmonary bypass, lengthy surgical procedures, and is associated with a variety of peri- and postoperative complications, with spinal cord ischemia, considered the most devastating.

TEVAR 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; for them, the procedure can be performed using a retroperitoneal approach.

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 (eg, paraplegia, cardiopulmonary events), and others are unique to TEVAR (eg, access site complications).

**OUTCOME MEASURES**
Controlled trials of specific patient groups treated with specific procedures are required to determine whether endovascular approaches are associated with equivalent or improved outcomes compared with surgical repair. For patients who are candidates for surgery, open surgical resection of the aneurysm with graft replacement is considered the criterion 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 with 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.

## FDA or Other Governmental Regulatory Approval

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

A number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) for use in TAAs (see Table 1).

**Table 1. Endovascular Grafts Approved for Use in Thoracic Aortic Aneurysms**

| Device | Manufacturer | Date Approved | PMA No. |
|---|---|---|---|
| GORE TAG® Thoracic Endoprosthesis | W.L. Gore and Associates | Mar 2005 | P040043 |
| Zenith TX2® TAA Endovascular Graft | Cook Europe | May 2008 | P070016 |
| Zenith Alpha™‡ Thoracic Endovascular Graft | Cook | Sep 2015 | P140016 |
| Talent™ Thoracic Stent Graft System | Medtronic Vascular | Jun 2008 | P070007 |
| Relay® Thoracic Stent-Graft with Plus Delivery System | Bolton Medical | Sep 2012 | P110038 |
| Valiant™ Thoracic Stent Graft with the Captivia® Delivery System | Medtronic Vascular | Apr 2011 | P100040 |

PMA: premarket approval.

The Gore TAG Thoracic Endoprosthesis is indicated 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 to 37 mm, and 2 cm or more nonaneurysmal aorta proximal and distal to the aneurysm. In 2012, FDA expanded the 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 to 42 mm, with 20 mm or more of nonaneurysmal aortic distal and proximal to the lesion.

The Zenith TX2 TAA Endovascular Graft was approved by FDA through the premarket approval (PMA) process for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta. Indicated aortic inner diameter ranges from 24 to 38 mm.

The Talent Thoracic Stent Graft System was approved by FDA through the PMA process for the endovascular repair of fusiform and saccular aneurysms or penetrating ulcers of the descending thoracic aorta. Indicated aortic inner diameter ranges from 18 to 42 mm.
The Relay®‡ Thoracic Stent-Graft with Plus Delivery System was approved by FDA through the PMA process for the endovascular repair of fusiform aneurysms and saccular aneurysms or penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac or femoral access vessel morphology compatible with vascular access techniques, devices, and/or accessories
- Nonaneurysmal aortic neck diameter ranging from 19 to 42 mm
- Nonaneurysmal proximal aortic neck length between 15 and 25 mm and nonaneurysmal distal aortic neck length between 25 and 30 mm, depending on the diameter stent graft required.

The Valiant™‡ Thoracic Stent Graft with the Captivia®‡ Delivery System was approved by FDA for isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers, and/or isolated hematomas, but not dissections. Indicated aortic diameter is 18 to 42 mm for aneurysms and

penetrating ulcers, and 18 to 44 mm for blunt traumatic injuries. In 2014, FDA expanded the indication for this graft and delivery system to include all lesions of the descending thoracic aorta, including type B dissections. The Valiant graft is intended for the endovascular repair of all lesions of the descending aorta in patients having appropriate anatomy, including:

- Iliac/femoral access vessel morphology compatible with vascular access techniques, devices, and/or accessories;
- Nonaneurysmal aortic diameter ranging from 18 to 42 mm (fusiform and saccular aneurysms/penetrating ulcers), 18 to 44 mm (blunt traumatic aortic injuries), or 20 to 44 mm (dissections) and;
- Nonaneurysmal aortic proximal and distal neck lengths of 20 mm or more (fusiform and saccular aneurysms/penetrating ulcers), and landing zone of 20 mm or more proximal to the primary entry tear (blunt traumatic aortic injuries, dissection). The proximal extent of the landing zone must not be dissected.

The expanded approval was based on the Medtronic Dissection Trial (NCT01114724), a prospective, nonrandomized study that evaluated the performance of the Valiant stent graft for acute, complicated type B dissection, which included 50 patients enrolled at 16 sites.

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

**Centers for Medicare and Medicaid Services (CMS)**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be

adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**ANEURYSMS OF THE DESCENDING THORACIC AORTA**

There are no RCTs assessing endovascular repair vs open surgery for thoracic aneurysms. The best evidence consists of nonrandomized comparative studies and systematic reviews of these studies. Representative prospective, nonrandomized studies, and selected systematic reviews are reviewed herein.

**Systematic Reviews**

An updated Cochrane review evaluating treatments for thoracic aneurysms was published by Abraha et al (2016). No RCTs comparing endovascular repair with open surgical interventions were identified. Reports from nonrandomized studies suggested 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, stent fractures, and aneurysm-related death. Patients receiving endovascular grafts also require more frequent surveillance with computed tomography scans with an increase in radiation exposure and will probably need surgical reintervention. Reviewers noted that high-quality RCTs are needed to evaluate longer term outcomes, but it is unlikely that such RCTs would be conducted with the current state endovascular practice.

**Nonrandomized 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 surgical repair (n=94; 50 historical, 44 concurrent) or stent grafting (n=140) at 17 U.S. sites. 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 after device deployment. The number of patients in the TAG 99-01 device group who experienced 1 or more major adverse event (42%) was significantly lower than the surgical repair control group (77%) at 1-year follow-up ($p<0.001$). Major adverse events included major bleeding as well as neurologic, pulmonary, renal function, and vascular complications. In the TAG 99-01 device group, 4 (3%) of 140 patients experienced paraplegia or paraparesis vs 13 (14%) of 94 patients in the control group. The Makaroun report (2005) of the TAG 99-01 study noted favorable aneurysm-related (97%) and overall survival (75%) rates and concluded that the Gore TAG device was a safe alternative treatment for descending thoracic aortic aneurysms (TAAs).

Makaroun et al (2008) reported on 5-year outcomes of the TAG 99-01 trial. In this follow-up of 140 endograft patients and 96 noncontemporaneous controls, the authors concluded that endovascular

treatment was superior to surgical repair at 5 years in anatomically suitable patients. At 5 years, the aneurysm-related mortality rate was lower for TAG patients (2.8%) than for open controls (11.7%; p=0.008). No differences in all-cause mortality rates 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 (3.6%) TAG patients had had major aneurysm-related reinterventions at 5 years. Compared with the 1-month baseline, sac size at 60 months decreased by 50% and increased in 19% of TAG patients. At 5 years, no ruptures, 1 migration, no collapse, and 20 instances of fracture in 19 patients were reported, all before the revision of the TAG graft. Trialists also suggested that, although sac enlargement was concerning, the modified device might help resolve this issue.

***VALOR and VALOR II Trials***

The Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) trial was a nonrandomized study conducted at 38 U.S. sites to assess the Talent stent graft. The VALOR trial enrolled candidates for open surgical repair and compared 195 TAA patients (age, 70.2 years; male, 59%) with 189 retrospective open surgical repair controls (age, 69.6 years; male, 52.4%). Thirty-day (Talent group, 4/195 vs surgery group, 15/189; p<0.1) and 12-month (Talent group, 31/192 vs surgery group, 39/189; p<0.01) mortality were lower in the endovascular graft group than in the open surgery group.

The Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft in the Treatment of Descending Thoracic of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair (VALOR II) was a prospective nonrandomized trial at 24 sites designed to evaluate the Valiant thoracic stent graft. VALOR II enrolled 160 patients who underwent stent grafting with the Valiant device, using enrollment criteria similar to VALOR. VALOR II outcomes were compared with those from the VALOR study. All-cause mortality at 12 months associated with the Valiant stent graft (12.6%) was statistically noninferior to the Talent stent graft (16.1%) and exceeded the primary effectiveness goal of 12-month successful aneurysm treatment (defined as absence of aneurysm growth >5 mm and of secondary procedures for type I/III endoleak).

Matsumoto et al (2014) reported on rates of secondary procedures over 3-year follow-up for patients enrolled in the VALOR and VALOR II trials. Three-year follow-up evaluations were available for 127 (65.5%) patients in the thoracic endovascular aneurysm repair (TEVAR) arm of VALOR and 96 (61.8%) in VALOR II. Freedom from secondary procedures at 3 years was 85.1% (95% confidence interval [CI], 78.5% to 89.8%) in the TEVAR arm of VALOR and 94.9% (95% CI, 88.8% to 97.7%) in VALOR II (p<0.001). The overall 3-year difference between groups in secondary procedure rates was driven by differences in early (<1 year) reintervention rates. This comparison suggested that the newer generation stent graft device may be associated with fewer reinterventions; however, the nonrandomized comparison and potential differences between patients in VALOR and VALOR II makes it difficult to draw firm conclusions about the relative efficacy of different devices.

***Matsumara et al***
The Zenith TX2 device received premarketing approval from the Food Drug Administration based on results of the trial reported by Matsumara et al (2008). This prospective cohort trial compared 160 TEVAR patients (age, 72 years; male, 72%) with 70 open surgery patients (age, 68 years; male, 60%). The trial arms were comparable in the 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 (98.1%) was noninferior to the control group (94.3%; $p<0.01$). The 30-day severe morbidity composite index (cumulative mean number of events per patient) was significantly lower in the endovascular group (0.2) than in the control group (0.7; $p<0.01$). At 12 months, aneurysm growth was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103), and stent migration in 2.8% (3/107). At 12 months, aneurysm enlargement was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103) of patients, and migration in 2.8% (3/107) of patients.

Matsumara et al (2014) published 5-year follow-up from the Zenith TX2 cohort trial. The 70 patients in the open surgical control group underwent clinical evaluation before discharge or at 1 month and then at 12 months and yearly after that, up to 5 years. TEVAR patients had follow-up at 1, 6, and 12 months postprocedure and yearly after that. Of the 160 TEVAR patients, 2 did not have successful device deployment and only had a follow-up to 30 days; an additional 32 were lost to follow-up. Five-year survival was 62.9% for the TEVAR group and 62.8% for the open surgical group ($p=0.88$). Kaplan-Meier estimates for freedom from severe morbidity was significantly higher in the TEVAR group than in the open surgical control group (87.3% vs 64.3% at 1 year; 79.1% vs 61.2% at 5 years; all $p<0.001$). Secondary interventions occurred at similar rates between the endovascular and open surgical control patient groups during follow-up through 5 years. While this trial is limited by some loss to follow-up, it did suggest that the early morbidity benefit associated with TEVAR persists over time and that rates of secondary interventions may be comparable with the open surgical repair.

**Section Summary: Aneurysms of the Descending Thoracic Aorta**
There are no RCTs comparing TEVAR with open surgery for elective repair of TAAs, with the best evidence on this question consisting of nonrandomized, comparative studies. 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 reported that long-term survival is better following open surgery. TEVAR patients have a higher rate of long-term complications, primarily from endoleaks, and a higher reintervention rate. TEVAR patients also require closer monitoring after the intervention, with more frequent imaging studies. The main limitation of these studies was the noncomparability of groups, with group differences demonstrated between endovascular and surgical patients in nearly all cases.

**DISSECTIONS OF THE DESCENDING THORACIC AORTA**

**Acute, Uncomplicated Type B Aortic Dissections**

***Randomized Controlled Trials***
One RCT (the ADSORB trial) compared TEVAR with best medical therapy for patients with acute, uncomplicated dissections. Initial results of the ADSORB trial, which randomized 61 patients with uncomplicated acute type B aortic dissection to best medical therapy (n=31) or to best medical therapy plus endovascular repair with the Gore TAG stent graft (n=30), were reported by Brunkwall et al (2014). Eligible patients had acute (randomized within 14 days of symptom onset), uncomplicated type B dissection without evidence of connective tissue disease. The median time from onset of symptoms to randomization was 4.8 and 4.6 days for the best medical therapy group and the TEVAR group, respectively. Treatment crossovers occurred in 3 patients from the best medical therapy group to the TEVAR group. Fourteen subjects failed due to inadequate or no imaging and were counted in the 1-year efficacy end point calculations as failures. The trial's primary end point was a composite of (1) incomplete or no false lumen thrombosis at 1 year, (2) aortic dilation at 1 year, or (3) aortic rupture through the 1-year follow-up period. At 1 year, 15 (50.0%) of the 30 TEVAR patients had at least 1 end point event, and all 31 best medical therapy patients had at least 1 end point event ($p<0.001$). In the control group, 30 patients had no false lumen thrombosis, and 14 had aortic dilatation; there were no cases of aortic rupture in either group. There were no deaths within 30 days postprocedure; during follow-up, 1 death (cardiac arrest) occurred in the TEVAR group.

***Section Summary: Acute, Uncomplicated Type B Aortic Dissections***
One RCT reported short-term improvements in aortic remodeling and risk of aortic dilation and rupture in patients with acute, uncomplicated aortic dissections treated with TEVAR, compared with those receiving best medical management. However, this trial was underpowered to evaluate mortality differences, and limitations included a high rate of failure of imaging follow-up.

**Acute, Complicated Type B Aorta Dissections**

***Systematic Reviews***
Moulakakis et al (2014) reported on results of a systematic review and meta-analysis of studies evaluating the management of complicated and uncomplicated type B aortic dissection, including medical management, open surgical repair, and endovascular repair. "Complicated dissections" were defined as those with aortic rupture, visceral and renal ischemia, lower-extremity ischemia, or spinal cord ischemia, or with expansion to the aortic arch or proximal descending aorta with a total diameter of 4.5 cm or more. Reviewers included 30 studies on TEVAR, 15 studies on best medical therapy, and 9 studies on surgical repair. For the 2531 patients with acute, complicated type B aortic dissection treated with TEVAR, the pooled 30-day/in-hospital mortality rate was 7.3% (95% CI, 5.3% to 9.6%). Survival rates ranged from 62% to 100% at 1 year and from 61% to 87% at 5 years. For the 1276 patients with acute complicated type B aortic dissection treated with open repair, the pooled 30-day/in-hospital mortality rate was 19.0% (95% CI, 16.8% to 21.1%). Survival rates ranged from 74.1% to 86.0% at 1 year and from 44.0% to 82.6% at 5 years.

Direct comparisons between treatment groups were not reported, and the trial did not account for between-group differences (other than treatment modality), which limits conclusions that may be drawn.

***Randomized Controlled Trials***
There are no RCTs for treatment of acute, complicated type B dissections, which is the group for which endovascular repair is often targeted.

***Nonrandomized Controlled Trials***
Fattori et al (2013) compared long-term survival for TEVAR with best medical therapy for acute, type B aortic dissections among patients enrolled in an international registry of acute aortic dissections. The multinational registry included 24 referral centers in 12 countries; the registry was designed to acquire data on an unbiased representative population of patients with acute aortic dissection. A total of 3865 patients were enrolled from 1995 to 2012. The Fattori study included 1129 patients who underwent medical therapy (n=853) or endovascular stent graft placement (n=276). Patients who underwent TEVAR were matched in 2:1 to medical therapy patients based on a propensity score created from a multivariable binary logistic regression model for the conditional probability for endovascular treatment vs medical treatment. The groups differed significantly at baseline: patients receiving endovascular treatment were more likely to present with clinical signs of malperfusion, such as leg pain (21.7% vs 8.4%, p<0.001) and limb ischemia (20.6% vs 4.8%, p<0.001), were more likely to have preoperative acute renal failure (21.4% vs 12.4%, p<0.001), any pulse deficit on presentation (28.3% vs 13.4%, p<0.001), and complicated dissections (defined by the presence of shock, periaortic hematoma, signs of malperfusion, stroke, spinal cord ischemia, mesenteric ischemia/infarction, and/or acute renal failure; 61.7% vs 37.2%, p<0.001). Kaplan-Meier survival estimates at 5 years showed that TEVAR patients (15.5%) had a lower death rate than best medical therapy patients (29.0%; p=0.018).

***Section Summary: Acute, Complicated Type B Aorta Dissections***
For patients with acute, complicated type B dissections, there is limited evidence from a systematic review of case series and a propensity-matched study, the latter of which reported a significant early survival advantage for patients treated with TEVAR. This evidence is limited by the noncomparability of treatment groups.

**Chronic Type B Aorta Dissections**
Stable or uncomplicated type B dissections differ from acute lesions in that there is no evidence of ischemia or extension over the period of observation that would necessitate emergency surgery.

***Systematic Reviews***
Thrumurthy et al (2011) performed a systematic review of endovascular repair for chronic type B dissections, defined as dissections that present with symptoms for more than 14 days. Seventeen studies were selected in this review, including of 1 RCT (the INSTEAD trial, discussed next) and 16 single-arm series. Of the 16 single-arm series, 2 were prospective and 14 were retrospective. At a median of 24 months of follow-up, the mortality rate was 9.2% for patients treated with TEVAR, ranging from 0% to 41% across studies. A total of 8.1% of patients had endoleaks over 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 ranged from 40% to 100% at 24-month follow-up across studies.

***Randomized Controlled Trials***

One RCT, the Investigation of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial, compared endovascular stents with best medical therapy for patients who had chronic, stable thoracic aorta dissections. The INSTEAD trial was reported by Neinaber et al (2010). Patients were randomized to elective stent graft placement plus medical management (n=72) or to medical management alone (n=68) to maintain arterial pressure below 120/80 mm Hg. The primary end point (all-cause mortality at 1 year) did not differ significantly between groups: the cumulative survival rate was 91.3% in the endovascular group and 97.0% in the medical management group (p=0.16). In addition, the aorta-related mortality rate did not differ (5.7% vs 3.0%, respectively; p=0.42). There were 2 cases of ischemic spinal cord injury, one in each group. Seven (10.6%) patients in the medical group crossed over to the stent graft group, and one from each group required open surgical intervention within the 12-month study period. An additional stent graft for false lumen expansion was required in six patients. A secondary measure of aortic remodeling was reported more frequently in the endovascular repair group (91.3% vs 19.4%, respectively; p<0.001), but the clinical significance of this finding is unknown. Three adverse neurologic events occurred in the endovascular group compared with in the medical-only arm. Trialists concluded that elective stent graft placement did not improve survival at 1 year.

Nienaber et al (2013) published long-term follow-up results from the INSTEAD trial (INSTEAD-XL). Patients were followed for a minimum 5 years (maximum, 8 years); the median interval until death or latest follow-up was 69 months (interquartile range, 62-83 months); there was no loss to follow-up. The risk of all-cause mortality did not differ significantly between groups at 5 years postrandomization (11.1% in the endovascular repair group vs 19.3% in the medical therapy group, p=0.13). For the combined end point of disease progression (aorta-specific death, crossover/conversion, secondary procedures) and aorta-specific events at 5 years of follow-up, freedom from the combined end point was 53.9% with medical therapy alone and 73.0% with TEVAR.

***Section Summary: Chronic Type B Aortic Dissections***

For patients with chronic, stable dissections of the thoracic aorta, an RCT reported that short-term outcomes did not differ significantly between TEVAR and medical management in stable patients with type B aortic dissection. The INSTEAD-XL findings suggested that preemptive endovascular repair may be associated with an excess risk of mortality and morbidity in the immediate postprocedural period, which is outweighed by a longer term survival benefit. The trialists noted that best medical management did not prevent late complications of aortic dissections, including expansion, rupture, and late crossover or conversion to emergent TEVAR.

**TEARS AND RUPTURE OF THE DESCENDING AORTA**

**Systematic Reviews**
A Cochrane review by Pang et al (2015) searched for published or unpublished RCTs to determine whether TEVAR for blunt traumatic thoracic aortic rupture would reduce mortality and morbidity compared with the open surgical repair. Reviewers did not identify any RCTs meeting their selection criteria.

***Ruptured Descending TAA***
Jonker et al (2010) conducted a meta-analysis of studies published between 1996 and 2009 to evaluate outcomes from open surgical repair (n=81) and endovascular repair (n=143) for ruptured descending TAA. The 30-day mortality was 19% for patients treated with endovascular repair and 33% for patients treated with open repair (p=0.016). During a median follow-up of 17 months, 5 additional patients in the endovascular group died of aneurysm-related causes, endoleaks were reported in 11.1% of patients, and endograft migration was reported in 1 patient. Reviewers noted that the durability and endovascular-related complications remain concerns.

***Traumatic Thoracic Aortic Injuries***
Lee et al (2011) summarized data on the use of TEVAR for traumatic thoracic aortic injuries to aid development of practice guidelines. The systematic review included 7768 patients from 139 studies. Reviewers found significantly lower mortality rates in patients who underwent endovascular repair, followed by open repair, and nonoperative management (9%, 19%, 46%, respectively, p<0.01). The evidence was of very low quality, and there was a lack of follow-up data.

**Nonrandomized Comparative Studies**
Ultee et al (2017) used the U.S. Nationwide Inpatient Sample database to identify 12,399 individuals who had a ruptured TAA between 1993 and 2012. Of these, 1622 (13%) underwent TEVAR, 2808 (23%) underwent open repair, and 7969 (64%) did not undergo surgical treatment. The use of TEVAR increased from 2% of total admissions in 2003-2004 to 43% in 2011 to 2012 (p<0.001). The greatest increase occurred in patients over 80 years of age. Both open surgical repair and nonoperative treatment decreased during this period. Patients treated with TEVAR were more likely to have diabetes, hypertension, coronary artery disease, and chronic kidney disease. Mortality rates for patients treated with TEVAR (22%) were lower than for those treated with open repair (33%; p<0.001). In adjusted analysis, the open repair was associated with twofold higher mortality than TEVAR (odds ratio, 2.0; 95% CI, 1.7 to 2.5).

**Section Summary: Tears and Rupture of the Descending Aorta**
The Food and Drug Administration approval was granted for endovascular stent graft treatment of thoracic artery ruptures in 2012. The evidence on TEVAR for treating thoracic artery rupture consists of single-arm series and nonrandomized comparative studies. There are no RCTs, but RCTs are likely difficult to complete for this indication because of its emergent nature. The available evidence has suggested that there are fewer early deaths and complications with TEVAR than with open surgery, but these data are limited by the noncomparability of treatment groups. Longer term outcomes are uncertain.

**PATHOLOGY OF THE ASCENDING AORTA**
Compared with its use for descending aortic pathologies, TEVAR has been less widely studied in the management of ascending aortic pathologies. Only small case series for the use of TEVAR for ascending aortic pathologies were identified. For example, Vallabhajosyula et al (2015) retrospectively reported on outcomes for 6 patients who underwent endovascular repair for ascending aorta pseudoaneurysm (n=4) or acute type A aortic dissection (n=2). Roselli et al (2015) described a series of 22 patients who underwent TEVAR of the ascending aorta for acute type A aortic dissection (n=9), intramural hematoma (n=2), pseudoaneurysm (n=9), chronic dissection (n=2), or aortocardiac fistula (n=2). Appoo et al (2015) reported on imaging-related outcomes for 16 patients who underwent TEVAR for aortic arch or ascending aorta.

**Section Summary: Pathology of the Ascending Aorta**
The evidence on the use of TEVAR for ascending aortic pathologies is limited to small case studies that have assessed heterogeneous patient populations.

**SUMMARY OF EVIDENCE**
For individuals who have type B (descending) thoracic aortic aneurysms who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. The available nonrandomized comparative studies have consistently reported reduced short-term mortality and morbidity compared with surgical repair. Although these types of studies are subject to selection bias and other methodologic limitations, the consistency of the findings of equivalent or reduced short-term mortality and fewer early complications across populations with different characteristics supports the conclusion that TEVAR is a safer procedure in the short term. The likely short-term benefits of TEVAR are mitigated by less favorable longer term outcomes, but longer term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have type B (descending) aortic dissections who receive endovascular repair, the evidence includes RCTs, systematic reviews, and nonrandomized comparative studies. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For acute uncomplicated type B dissections, an RCT has reported short-term improvements in aortic remodeling and a decreased risk of aortic dilation and rupture in patients treated with TEVAR compared with best medical management. However, this trial was underpowered to evaluate mortality differences, and limitations included a high TEVAR failure rate based on imaging follow-up. For acutely complicated type B dissections, there are no RCTs. Short- and intermediate-term results from a systematic review of observational studies that compared TEVAR with open surgery has suggested a benefit for TEVAR in complicated (organ or limb ischemia or rupture) type B dissection. However, this evidence is limited by selection bias and baseline differences between groups and therefore is not definitive on the efficacy of TEVAR vs open surgery. For chronic type B dissections, evidence from an RCT did not demonstrate short-term outcome benefits associated with TEVAR; however, after more than 5 years of follow-up, TEVAR was associated with a survival benefit beginning 2 years postprocedure. Additional evidence from high-quality trials is needed to

determine whether TEVAR improves outcomes for patients having type B aortic dissections. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have traumatic descending aortic tears or rupture who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For traumatic thoracic aortic injury and rupture, nonrandomized comparative data have suggested a benefit for TEVAR in reducing periprocedural mortality and morbidity. Although it is expected that RCTs will be difficult to conduct for this indication (due to its emergent nature), the risks of bias in the available nonrandomized studies are high, raising uncertainty about results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have ascending aortic disorders who receive endovascular repair, the evidence includes small case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For patients with ascending aortic pathologies, including dissections, aneurysms, and other disorders, the evidence on the use of TEVAR is limited to small series that have assessed heterogeneous patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy # 00181
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Current Effective Date: 11/21/2018

## Policy History

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|---|---|
| 09/07/2005 | Medical Director review |
| 09/20/2005 | Medical Policy Committee review |
| 09/22/2005 | Quality Care Advisory Council approval |
| 05/03/2006 | Medical Director review |
| 05/17/2006 | Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. |
| 11/07/2007 | Medical Director review |
| 11/15/2007 | Medical Policy Committee approval. Coverage eligibility unchanged. |
| 11/05/2008 | Medical Director review |
| 11/18/2008 | Medical Policy Committee approval. Coverage eligibility unchanged. |
| 11/12/2009 | Medical Policy Committee approval |
| 11/18/2009 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 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 *Note* 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. |
| 11/06/2014 | Medical Policy Committee review |
| 11/21/2014 | Medical Policy Implementation Committee approval. Title changed from “Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections” to “Endovascular Stent Grafts for Disorders of the Thoracic Aorta”. Coverage eligibility unchanged. |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 10/29/2015 | Medical Policy Committee review |
| 11/16/2015 | Medical Policy Implementation Committee approval. Updated INV statement. |
| 11/03/2016 | Medical Policy Committee review |
| 11/16/2016 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 11/02/2017 | Medical Policy Committee review |
| 11/15/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 01/01/2018 | Coding update |
| 11/08/2018 | Medical Policy Committee review |
| 11/21/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Moved the *“Note”* from the coverage section to a newly created Policy Guidelines section. |

Next Scheduled Review Date: 11/2019

## Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 33880, 33881, 33883, 33884, 33886, 33889, 33891, 75956, 75957, 75958, 75959 |
| HCPCS | No codes |
| ICD-10 Diagnosis | I71.00-I71.01, I71.1-I71.8, S25.101A-S25.109A, S25.111A-S25.119A, S25.121A-S25.129A, S25.191A-S25.199A |

*****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.

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.