Endovascular Stent Grafts for Disorders of the Thoracic Aorta

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Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for endovascular stent grafts for disorders of the thoracic aorta when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Endovascular stent grafts may be considered medically necessary for the treatment of descending thoracic aortic aneurysms without dissection using devices approved by the U.S. Food and Drug Administration for their approved specifications (see Considerations section).

Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration may also be considered medically necessary in the following situations:
- Treatment of acute, complicated (organ or limb ischemia or rupture) Type B thoracic aortic dissection

Endovascular stent grafts may be considered medically necessary for the treatment of rupture of the descending thoracic aorta.

When Policy Topic is not covered
Endovascular stent grafts are considered investigational for the treatment of thoracic aortic lesions that do not meet the above criteria, including but not limited to thoracic aortic arch aneurysms.

Considerations
Endograft placement relies on non-aneurysmal aortic segments proximal and distal to the aneurysm and/or dissection for anchoring, and a maximal graft diameter that varies by device. The GORE TAG® endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for “>2 cm non-aneurysmal aorta proximal and distal to the aneurysm and an “aortic inner diameter of 23–37 mm.” The Talent™ Thoracic Stent Graft System is approved by the FDA for “non-aneurysmal aortic proximal and distal neck lengths >20mm” and “non-aneurysmal aortic..."
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 treatment of thoracic aortic aneurysms, dissections, or rupture, and thus has the potential to reduce the morbidity and mortality of open surgery. Endovascular stenting may also be an alternative treatment to medical therapy for thoracic aortic aneurysms or thoracic aorta dissections.

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 morbidity and mortality. The available nonrandomized comparative studies have consistently reported reduced short-
term morbidity and mortality 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 qualitatively 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 randomized controlled trials (RCTs), systematic reviews, and nonrandomized comparative studies. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. For acute uncomplicated type B dissections, 1 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 include a high TEVAR failure rate based on imaging follow-up. For acute 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 suggest 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 versus open surgery. For chronic type B dissections, the evidence from 1 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 post-procedure. 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 morbidity and mortality. For traumatic thoracic aortic injury and rupture, nonrandomized comparative data has suggested a benefit for TEVAR in reducing periprocedural morbidity and mortality. 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 is high. 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 morbidity and mortality. For patients with ascending aortic pathologies, including dissections, aneurysms, and other disorders, the evidence on use of TEVAR is limited to small series that assess
heterogeneous patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

Formal clinical input demonstrated support for the use of TEVAR for complicated type B dissections, and in certain cases of traumatic thoracic aortic injury and rupture.

**Background**

**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 thoracic aortic aneurysm (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. (1) 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. (2) 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 6.5 cm. (3)
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. (1, 4) 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. (5, 6) 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, hypothermia with circulatory arrest, and evoked potential monitoring. (7-10) However, the optimal protective strategy is still uncertain. (11)

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. (12) 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.

**Thoracic Endovascular Aneurysm Repair.** 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 thoracic aortic aneurysm (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.

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, 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.
Regulatory Status
A number of endovascular grafts are approved for use in thoracic aortic aneurysms (TAAs; see Table 1).

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

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

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 January 2012, the Food and Drug Administration 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 is in the range of 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 that is compatible with vascular access techniques, devices, and/or accessories
- Nonaneurysmal aortic neck diameter in the range of 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 January 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 that is compatible with vascular access techniques, devices, and/or accessories;
- Nonaneurysmal aortic diameter in the range of 18 to 42 mm (fusiform and saccular aneurysms/penetrating ulcers), 18 to 44 mm (blunt traumatic aortic injuries [BTAI]), or 20 to 44 mm (dissections) and;
- Nonaneurysmal aortic proximal and distal neck lengths 20 mm or more (fusiform and saccular aneurysms/penetrating ulcers), and landing zone 20 mm or more proximal to the primary entry tear (BTAI, 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.

**Rationale**

This evidence review was originally created in December 2002 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through March 23, 2017.

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.

Randomization to treatment groups is also very important in the evaluation of endovascular repair of thoracic aortic disorders. This is due to the numerous patient factors (eg, age, comorbidities, location and size of the aneurysm, presence or absence of dissection) and procedure variables involved in surgical repair that are potential confounders of outcome. Selection for open or endovascular repair involves a complex set of patient and anatomic considerations. As a result, studies are highly prone to selection bias if there is no randomized assignment. The following is a summary of key findings.

### 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 nonrandomized comparative studies and systematic reviews of these studies. We assessed representative prospective, nonrandomized studies, and selected systematic reviews.

### Systematic Reviews

An updated Cochrane review by Abraha et al was published in 2016. No RCTs comparing endovascular repair to open surgical interventions for thoracic aneurysms were found in the medical literature. Reports from nonrandomized studies have 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.

In 2016, Biancari et al published a systematic review of thoracic endovascular aneurysm repair (TEVAR) for aneurysms of the descending thoracic aorta in the elderly (mean, 72.6 years; 95% confidence interval [CI], 71.3 to 73.9 years). No RCTs were identified, and reviewers did not compare TEVAR with open surgical repair in this more fragile population. The 11 observational studies (673 patients, 6 retrospective) reported technical success in 91.0% of procedures, with vascular access complications requiring repair in 9.7% of cases. Endoleak was observed in 10.5% of patients. Survival rates were 96.0% at 30 days, 80.3% at 1 year, 77.3% at 2 years, and 74.0% at 3 years. TEVAR as an emergency procedure was performed in about one-third of the population, and this population had a significantly higher 30-day mortality rate than elective TEVAR (17.1% vs 1.8%; relative risk [RR], 3.83; 95% CI, 1.18 to 12.40; p=0.025). By 3 years, reintervention was needed in 9.7% of patients, with death secondary to aneurysm...
rupture and/or fistula in 3.2% of patients. Interpretation of these results is difficult due to the lack of comparison with open repair.

**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 versus 13 (14%) of 94 patients in the control group. The Makaroun report (2005) of the TAG 99-01 study reported favorable aneurysm-related (97%) and overall survival (OS) (75%) rates, and concluded that the Gore TAG device was a safe alternative treatment for descending thoracic aortic aneurysms (TAAs).

In 2008, Makaroun et al reported 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, aneurysm-related mortality was lower for TAG patients (2.8%) compared with open controls (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 (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 in 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 patients who were 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%). Patients in the Talent endovascular graft group had smaller TAA size and were less likely to have had a previous aortic aneurysm (37/195 vs 70/189 in the surgery group). Talent subjects were also less likely to have comorbid conditions, including angina (pooled RR=1.6; 95% CI, 1.0 to 2.6), coronary artery disease (pooled RR=1.2; 95% CI, 1.0 to 1.5), or previous myocardial infarction (MI; pooled RR=1.3; 95% CI, 1.0 to 1.6). 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. Fewer endovascular graft patients required blood transfusions (Talent, 22% vs surgery, 93%). Endovascular graft patients had a shorter intensive care unit stay (Talent, 2 days vs surgery, 8 days) and overall hospital stay (Talent, 6 days vs surgery, 17 days).

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 study 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 outcomes were compared with those from the VALOR study. Stent-graft delivery was technically successful in 154 patients. Hundred fifty-one patients were evaluated at 12 months postprocedure; 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).

In 2014, Matsumoto et al reported 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 TEVAR arm of VALOR and for 96 (61.8%) in VALOR II. Freedom from secondary procedures at 3 years was 85.1% (95% 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.

Goodney et al
Goodney et al (2011) used Medicare claims data from 1998 to 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 2433 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 1100 patients.

Thirty-day mortality was slightly lower among TEVAR patients (6.1%) than among open surgery patients (7.1%), but this difference was not statistically significant (p=0.07). In the propensity-matched comparison, there was no difference in 30-day mortality between the TEVAR group (4.5%) and open surgery group (4.2%; p=0.78). Long-term survival was reported using Cox proportional hazards analysis. At 5 years, survival in the TEVAR group (62%) was lower than in the open surgery group (72%; p=0.001). In the propensity-matched comparison, the TEVAR group (73%) also had lower OS at 5 years than the open surgery group (81%; p=0.007).

Matsumara et al
The Zenith TX2 device received premarketing approval from FDA based on results of the trial reported by Matsumara et al (2008). This prospective cohort trial compared 160 thoracic endovascular aneurysm repair patients (age, 72 years; male, 72%) with 70 open surgery patients (age, 68 years; male, 60%). The trial 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 (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.

In 2014, Matsumara et al 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 thereafter up to 5 years. TEVAR patients had follow-up at 1, 6, and 12 months postprocedure and yearly thereafter. Of the 160 TEVAR patients, 2 did not have successful device deployment and only had 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=NS). Kaplan-Meier estimates for freedom from severe morbidity composite index 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 open surgical repair.
Other Studies
In addition to the prospective studies described above, other studies have compared open and endovascular repair using either large administrative databases or retrospective comparative designs. Orandi et al (2009) published a comparative analysis of 1030 patients undergoing open surgery and 267 undergoing endovascular repair using the Nationwide Inpatient Sample database. In-hospital mortality rates were similar between open and endovascular patients (adjusted odds ratio [OR], 1.2; 95% CI, 0.73 to 2.12). Dick et al (2008) reported a post hoc analysis of prospectively collected data for clinical and quality-of-life outcomes in 52 patients undergoing endovascular repair with 70 patients undergoing open surgical repair, and reported no significant differences in perioperative mortality rates or overall quality-of-life scores. Other representative retrospective studies of TEVAR for aortic aneurysms are those by Cazavet et al (2016), Iba et al (2014), and Arnaoutakis et al (2015).

Section Summary: Aneurysms of the Descending Thoracic Aorta
There are no RCTs of TEVAR versus open surgery for elective repair of thoracic aortic aneurysms, with the best evidence on this question consisting of nonrandomized, comparative studies. The main limitation of these studies is noncomparability 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. 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 intervention, with more frequent imaging studies.

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. In 2014, 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 published. 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 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.

**Nonrandomized Comparative Studies**

One retrospective study (2010) 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 to 36 months and did not differ between the medical therapy group (24%) and the endovascular group (23.7%; p=NS).

**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 treated with 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**

In 2014, Moulakakis et al reported on results of a systematic review and meta-analysis of studies on 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 extremities 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%
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 between TEVAR and 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 provide an unbiased representative population of patients with acute aortic dissection. A total of 3865 patients were enrolled from December 1995 to January 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 versus 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. There were 17 publications 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, mortality was 9.2% for patients treated with TEVAR, with a range of 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 occurred in a range of 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 to best medical therapy for patients with chronic, stable thoracic aorta dissections. The INSTEAD trial was reported in 2010. Patients were randomized to elective stent-graft placement in addition to medical management (n=72) or to medical management alone (n=68) to maintain arterial pressure below 120/80 mm Hg. The primary end point of all-cause mortality at 1 year did not differ significantly between the 2 groups: cumulative survival was 91.3% in the endovascular group and 97.0% in the medical management 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, 1 case in each group. Seven (10.6%) patients in the medical group crossed over to the stent-graft group, and 1 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 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. The trialists concluded that elective stent-graft placement did not improve survival at 1 year.

In 2013, Nienaber et al 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. Twenty-one additional TEVAR procedures were performed in the 5-year follow-up period, 14 in the medical therapy group (5 emergency cases), with conversion to open repair in 4 cases, and 7 in the TEVAR group, with conversion to open repair in 3 cases. 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). However, Kaplan-Meier curves demonstrated a survival benefit in the endovascular repair group between years 2 and 5 postrandomization (100% in the endovascular group vs 83.1% in the medical therapy group, p<0.001). Patients randomized to endovascular repair had lower aorta-specific mortality (6.9% vs 19.3%, p=0.04) and progression of aortic pathology (27.1% vs 46.1%, p=0.04). 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. Landmark
analysis was performed to compare hazard ratios (HRs) for events occurring up to and beyond 24 months postrandomization to assess for a time-dependent response to treatment. In that landmark analysis, the groups had similar patterns of freedom from progression of aortic disease up to 2 years (76.1% vs 75.5%; HR=0.997; 95% CI, 0.51 to 1.95; p=0.994); however, from 2 to 5 years of follow-up, the TEVAR group was more likely to be free from disease progression than the medical therapy group (95.9% vs 71.9%; HR=0.112; 95% CI, 0.03 to 0.49; p=0.004).

The INSTEAD-XL findings suggest that, in stable patients with type B aortic dissection, 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/conversion to emergent TEVAR.

**Nonrandomized Comparative Trials**
A number of studies have compared outcomes for open and endovascular repair or endovascular repair and best medical therapy using prospective or retrospectively collected data. In 2013, Jia et al reported a prospective, multicenter, nonrandomized comparative study of TEVAR versus medical therapy for chronic type B thoracic aortic dissections. A total of 208 patients were treated with TEVAR and 95 patients were treated with medical therapy. In the TEVAR group, no periprocedural deaths were reported, but there were serious complications (retrograde type A dissection, brachial artery pseudoaneurysm, paraplegia, MI) in 12 (5.8%) patients. Estimated survival rates at 2 and 4 years were 87.5% and 82.7% with TEVAR and 77.5% and 69.1% with medical therapy, respectively, but this difference was not statistically significant (p=0.068). The estimated rates of freedom from aorta-related death at 2 and 4 years were 91.6% and 88.1% for the TEVAR group and 82.8% and 73.8% with medical therapy, both respectively, a difference that was statistically significant (p=0.039).

**Section Summary: Chronic Type B Aortic Dissections**
For patients with chronic, stable dissections of the thoracic aorta, 1 RCT reported that short-term outcomes did not differ significantly between TEVAR and medical management. However, over 5 years of follow-up, patients who have had preemptive endovascular repair may demonstrate reduced morbidity and mortality.

**Tears and Rupture of the Descending Aorta**

**Systematic Reviews**
In 2010, Jonker et al published 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). The 30-day incidence of MI was 3.5% for those treated with endovascular repair and 11.1% in patients treated with open
repair (p<0.05). Rates of stroke and paraplegia were also increased in the surgically treated patients (p=NS). Additional vascular interventions were performed in 9.1% of endovascular patients and 2.3% of surgical patients (p=0.169). 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. Interpretation of these data are uncertain given the nonrandom treatment assignment.

Lee et al (2011) summarized data on the use of TEVAR for traumatic thoracic aortic injuries to aid development of practice guidelines.38 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. They suggested 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. They did, however, note that these conclusions be tempered by the lack of suitable (anatomic fit) devices, which can cause severe complications, and the lack of follow-up data.

A 2015 Cochrane review searched for published or unpublished RCTs to determine whether TEVAR for blunt traumatic thoracic aortic rupture would reduce mortality and morbidity compared with open surgical repair.39 The authors did not identify any RCTs meeting their selection criteria.

**Nonrandomized Comparative Studies**

The nonrandomized study by Azizzadeh et al (2013) compared outcomes for TEVAR and open surgery using prospectively collected data in 106 consecutive patients from a single institution between 2002 and 2010.40 Fifty-six patients underwent open surgery and 50 underwent TEVAR, with TEVAR being the preferred treatment option after it adoption at this institution. Primary outcomes were in-hospital death and complications. Death occurred in 5 (8.9%) of 56 patients undergoing open surgery compared with 2 (4.0%) of 50 patients who had TEVAR. The overall likelihood of complications, including death, was significantly lower in the TEVAR group (OR=0.33; 95% CI, 0.11 to 0.97). The number of patients with at least 1 complication was also greater in the open surgery group (70%) than in the TEVAR group (48%).

Goodney et al (2011) used Medicare claims data from 1998 to 2007 to compare TEVAR with open surgery in patients with aeurysms of the descending aorta.21 This study included patient with both intact and ruptured aeurysms. A total of 1307 patients with ruptured aeurysms were identified: 1008 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 had various medical comorbidities. Thirty-day mortality was significantly lower among TEVAR patients (28.4%) than in open surgery patients (45.6%; p<0.001). Long-term
survival was reported using Cox proportional hazards analysis. At 5 years, survival was low in both groups, with no significant difference between the TEVAR group (23%) and open surgery group (26%; \( p=0.37 \)).

Gopaldas et al (2011) used the U.S. Nationwide Inpatient Sample database to identify those who had had procedures to repair a thoracic artery rupture. A total of 923 patients were identified between 2006 and 2008, of whom 364 (39.4%) underwent TEVAR and 559 (60.6%) underwent open repair. Patients undergoing TEVAR were older and had a significantly higher burden of comorbidities than patients undergoing open repair. Overall mortality was 23.4% for TEVAR and 28.6% for open repair (\( p=\text{NS} \)). There were also no differences between groups in complication rates. TEVAR patients were more likely to have routine discharge from the hospital to home compared with open surgery patients (OR=3.3, \( p<0.001 \)).

**Observational Studies**

*FDA-Approval Studies (Single-Arm)*

Data from 2 uncontrolled clinical series of patients with isolated thoracic artery lesions were reviewed by 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 Gore TAG endograft, although 6 (11.8%) patients required deployment of 2 stent grafts for adequate coverage. There were 4 deaths within 30 days of treatment (7.8%; 95% CI, 3.1% to 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%) and 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. No patients had such an event requiring reintervention. Two patients were identified with type II endoleaks, but neither required reintervention.

A similar study (RESCUE) was submitted to 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 (perioperative mortality rate, 8%). Serious adverse events occurred in 12% of patients, most of which were procedure-related events (eg, femoral artery dissection, localized hematoma, hemothorax). Three patients required left subclavian artery revascularization to treat arm ischemia.

**Section Summary: Tears and Rupture of the Descending Aorta**

FDA 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 RCTs, but RCTs are likely difficult to complete for this indication because of the 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. The longer
term outcomes are uncertain, with no discernible differences between TEVAR and open surgery.

**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 use of TEVAR for ascending aortic pathologies were identified. For example, Vallabhajosyula et al (2015) retrospectively reported 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 imaging-related outcomes for 16 patients who underwent TEVAR for aortic arch or ascending aorta.

**Section Summary: Pathology of the Ascending Aorta**

The evidence related to the use of TEVAR for ascending aortic pathologies is limited to small case studies that include 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 thoracic endovascular aneurysm repair (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 randomized controlled trials (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, 1 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 include a high TEVAR failure rate based on imaging follow-up. For acute 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 versus open surgery. For chronic type B dissections, the evidence from 1 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 has 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. 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 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.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 4 academic medical centers (5 reviewers) while this policy was under review in 2011. Most providing input supported use of thoracic endovascular aneurysm repair in complicated type B aortic dissections and, in certain cases, in traumatic thoracic aortic injury.

Practice Guidelines and Position Statements
European Association for Cardio-Thoracic Surgery et al
The European Association for Cardio-Thoracic Surgery, the European Society of Cardiology, and the European Association of Percutaneous Cardiovascular Interventions published a joint position statement on thoracic endovascular aneurysm repair (TEVAR) in 2012. This document made the following statements on the use of TEVAR:

- **Thoracic aortic aneurysms**
  - TEVAR is indicated for asymptomatic patients when the maximum diameter of the aneurysm exceeds 5.5 cm or if rapid expansion occurs (>5 mm in 6 months).
  - It may be appropriate to select a larger aortic diameter threshold in patients with increased operative risk.

- **Type B aortic dissections**
  - For acute, complicated type B dissections, TEVAR is the treatment of choice.
  - For chronic, complicated type B dissections, the treatment approach should be discussed by an interdisciplinary team, considering the risks and benefits of open surgery versus TEVAR.
  - For uncomplicated type B dissections, a primary conservative approach with close surveillance for complications is justified.

- **Traumatic aortic injury**
  - Immediate endovascular treatment is indicated for patients with complete transection of the aortic wall and free bleeding into the mediastinum, or the presence of pseudocoarctation syndrome.
  - Delayed endovascular treatment can be considered when there is limited disruption of the aorta with intact media and adventitia.

American College of Cardiology Foundation et al
In 2010, a joint task force, of the American College of Cardiology Foundation, American Heart Association, and 8 other medical specialty societies, published guidelines on the diagnosis and management of descending thoracic and thoracoabdominal aortic aneurysms. The task force offered the following recommendations (see Table 2).

**Table 2. Joint Guidelines on Descending Thoracic and Thoracoabdominal Aortic Aneurysms**

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

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 3.

### Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01852773</td>
<td>Thoracic Endovascular Repair Versus Open Surgery for Blunt Injury</td>
<td>1300</td>
<td>May 2018</td>
</tr>
<tr>
<td>NCT02010892</td>
<td>Effective Treatments for Thoracic Aortic Aneurysms (ETTAA Study): A Prospective Cohort Study</td>
<td>2200</td>
<td>Jul 2019</td>
</tr>
<tr>
<td>NCT02043691</td>
<td>Evaluation of All-Cause Mortality and Pulmonary Morbidity in Treating Juxtarenal, Suprarenal and Thoracoabdominal Aortic Pathologies Using the Cook Custom Aortic Endograft, the Zenith t-Branch Endovascular Graft and Surgeon-Modified Endografts</td>
<td>30</td>
<td>Oct 2021</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT00111176a</td>
<td>Study of Thoracic Aortic Aneurysm Repair With the Zenith TX2 Endovascular Graft</td>
<td>260</td>
<td>May 2013 (completed)</td>
</tr>
<tr>
<td>NCT00742274a</td>
<td>A Randomized European Study Comparing Endoluminal Stent Grafting and Best Medical Therapy (BMT) to BMT Alone in the Treatment of Acute Uncomplicated Type B Aortic Dissection</td>
<td>61</td>
<td>Aug 2013 (completed)</td>
</tr>
<tr>
<td>NCT00435942a</td>
<td>Phase II Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft in Patients With Thoracic Aortic Pathologies</td>
<td>120</td>
<td>May 2015 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

**References**


Billing Coding/Physician Documentation Information

33880 Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin

33881 Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of the left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin

33883 Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension

33884 Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure)

33886 Placement of distal extension prosthesis delayed after endovascular repair of descending thoracic aorta

33889 Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral

75956 Endovascular repair of descending thoracic aorta (e.g., aneurysm,
pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation

75957 Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of the left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation

75958 Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption), radiological supervision and interpretation

75959 Placement of distal extension prosthesis (delayed) after endovascular repair of descending thoracic aorta, as needed, to level of celiac origin, radiological supervision and interpretation

ICD-10 Codes

I71.01 Dissection of thoracic aorta
I71.1- Thoracic aortic aneurysm, code range
I71.2
I71.5- Thoracoabdominal aortic aneurysm, code range
I71.6
S25.00xA- Injury of thoracic aorta, code range
S25.09xS

Additional Policy Key Words
N/A

Policy Implementation/Update Information

5/1/06 New policy.
5/1/07 No policy statement changes.
5/1/08 No policy statement changes.
5/1/09 No policy statement changes.
5/1/10 No policy statement changes.
5/1/11 Policy statement revised to indicate that use in treatment of uncomplicated dissections is investigational.
5/1/12 Policy statement revised to indicate may be considered medically necessary for complicated Type B dissections.
5/1/13 No policy statement changes.
9/1/13 Medically necessary indication added for acute rupture of the thoracic aorta.
9/1/14 Changed the wording of the investigational policy, but no change in the intent of the statement. No other policy statement changes.
9/1/15 No policy statement changes.
9/1/16  CPT code 33891 removed from policy. It was included in error. No policy statement changes.
9/1/17  No policy statement changes.

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