

<b>7.01.86</b>	<b>Endovascular Stent Grafts for Disorders of the Thoracic Aorta</b>		
<b>Original Policy Date:</b>	September 27, 2013	<b>Effective Date:</b>	December 1, 2023
<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 29

## Policy Statement

- I. Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** for the treatment of **any** of the following:
  - A. Descending thoracic aortic aneurysms used according to FDA-approved specifications (see Policy Guidelines section)
  - B. Acute, complicated (organ or limb ischemia or rupture) type B thoracic aortic dissection
  - C. Traumatic descending aortic tears or rupture
- II. Endovascular stent grafts are considered **investigational** for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated aortic dissection.
- III. Endovascular stent grafts are considered **investigational** for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

### Endograft Placement

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.

For example, the Gore TAG<sup>®</sup> endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for "greater than or equal to 2 cm non-aneurysmal aorta proximal and distal to the aneurysm" and an "aortic inner diameter of 23-37 mm."

The Zenith TX2<sup>®</sup> device is approved by the 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."

### Uncomplicated Type B Aortic Dissection with Indication for Intervention

Guidelines generally suggest medical management for most patients with uncomplicated type B aortic dissection. However, guidelines by the American College of Cardiology/American Heart Association (ACC/AHA) and Society of Thoracic Surgeons/American Association for Thoracic Surgery suggest that early, pre-emptive intervention may be considered in patients with uncomplicated acute type B aortic dissection who have high-risk features. The high-risk criteria suggested by ACC/AHA are: maximal aortic diameter >40 mm, false-lumen diameter >20-22 mm, entry tear >10 mm, entry tear on lesser curvature, increase in total aortic diameter of >5 mm between serial imaging studies, bloody pleural effusion, imaging-only evidence of malperfusion, refractory hypertension despite >3 different classes of antihypertensive medications at maximal recommended or tolerated doses, refractory pain persisting >12 hours despite maximal recommended or tolerated doses, or need for readmission. In patients with an indication for early intervention, guidelines suggest endovascular repair may be preferred for patients with suitable anatomy but who are at high risk for complications of open repair due to comorbidities.

## Coding

There are specific category I CPT codes for these procedures:

- **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 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(s) delayed after endovascular repair of descending thoracic aorta
- **33889:** Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral
- **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 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(s) (delayed) after endovascular repair of descending thoracic aorta, as needed, to level of celiac origin, radiological supervision and interpretation

## Description

Thoracic endovascular aortic repair (TEVAR) involves the percutaneous placement of a stent graft in the descending thoracic or thoracoabdominal aorta. It is a less invasive alternative than open surgery for the treatment of thoracic aortic aneurysms (TAAs), dissections, or rupture, and thus has the potential to reduce the morbidity and mortality of open surgery. Endovascular stenting may also be an alternative to medical therapy for treating TAAs or thoracic aorta dissections.

## Related Policies

- N/A

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

A number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) for use in TAAs (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, the 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 aorta distal and proximal to the lesion.

The Zenith TX2® TAA Endovascular Graft was approved by the 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 the 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 Talent Thoracic Stent Graft System was discontinued by the manufacturer and replaced with the Valiant™ Thoracic Stent Graft System.

The Relay® Thoracic Stent-Graft with Plus Delivery System was approved by the 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 the 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, the FDA expanded the indication for this graft and delivery system to include all lesions of the descending thoracic aorta, including type B dissections.<sup>13</sup> 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.

The Valiant Navion™ is a next generation thoracic stent graft system with a modified design of the Valiant Thoracic Stent Graft with Captivia Delivery System.<sup>14</sup> However, unused Valiant Navion thoracic stent graft systems were voluntarily recalled by the manufacturer (Medtronic) in February 2021 due to endoleaks, stent fractures, and stent ring enlargement.<sup>15</sup> The recall occurred due to results of the Valiant Evo Global Clinical Trial which found 3 patients with stent fractures, 2 of whom had confirmed type IIIb endoleaks, and 1 patient death. Further investigation by an independent imaging laboratory found 7 of 87 patients with stent ring enlargement. The manufacturer is conducting further analysis.

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.

## Rationale

### Background

#### 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 (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 et al (1998) performed a population-based study of TAA diagnosed in Minnesota, between 1980 and 1994.<sup>1</sup> 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 et al (2002) reported on the yearly rupture or dissection rates in 721 patients with TAA.<sup>2</sup> 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.<sup>3</sup>

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 complication, 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.<sup>1,4</sup> In elective cases, predictors of operative mortality include renal insufficiency, increasing age, symptomatic aneurysm, the presence of dissection, and other comorbidities (e.g., 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.<sup>5,6</sup> 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.<sup>7,8,9,10</sup> However, the optimal protective strategy is still uncertain.<sup>11</sup>

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 (i.e., 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 (i.e., shock or visceral ischemia), surgical intervention is usually indicated. Although there is an estimated 1-year survival rate of 50% in those treated with an open surgical procedure, it is not clear whether that rate is any better or worse for those treated medically.<sup>12</sup> The advent of stent grafting, with the potential of reducing the 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 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 aortic 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 Aortic Repair**

TEVAR is an alternative to open surgery. It 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 (e.g., paraplegia, cardiopulmonary events), and others are unique to TEVAR (e.g., 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.

### **Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the 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 1 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. Randomized controlled trials 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**

#### **Clinical Context and Therapy Purpose**

The purpose of endovascular repair is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with type B (descending) thoracic aortic aneurysms (TAAs).

The question addressed in this evidence review is: Does the use of endovascular repair improve the net health outcome in patients with type B (descending) TAA?

The following PICO was used to select literature to inform this review.

#### ***Populations***

The relevant population of interest are individuals with type B (descending) TAAs.

#### ***Interventions***

The therapy being considered is endovascular repair. Thoracic endovascular aortic repair (TEVAR) is the current standard of care for repairs of descending TAAs in patients with suitable anatomy, as there is a significant morbidity and mortality benefit when compared to open surgical repair.<sup>16</sup>

#### ***Comparators***

The following practice is currently being used to treat type B (descending) TAAs: open surgical repair or medical management.

#### ***Outcomes***

The general outcomes of interest are overall survival (OS), morbid events, treatment-related mortality, and treatment-related morbidity. Follow-up of at least 5 years is of interest to monitor outcomes.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

There are no RCTs assessing endovascular repair versus 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. Also, since TEVAR is the current standard of care for repairs of descending TAAs in patients with suitable anatomy, for this section, the addition of newer publications that address important safety concerns and/or patient selection criteria is prioritized.

### Systematic Reviews

An updated Cochrane review evaluating treatments for thoracic aneurysms was published by Abraha et al (2016).<sup>17</sup> 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 quality RCTs are needed to evaluate longer term outcomes, but it is unlikely that such RCTs would be conducted with the current state of 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.<sup>18</sup> 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 events (42%) was significantly lower than the surgical repair control group (77%) at 1-year follow-up (p<.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 noted favorable aneurysm-related (97%) and OS (75%) rates and concluded that the Gore TAG device was a safe alternative treatment for descending TAAs.

Makaroun et al (2008) reported on 5-year outcomes of the TAG 99-01 trial.<sup>19</sup> 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=.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 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.<sup>20</sup> 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;  $p < .1$ ) and 12-month (Talent group, 31/192 vs. surgery group, 39/189;  $p < .01$ ) mortality was 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.<sup>21</sup> The VALOR II trial enrolled 160 patients who underwent stent grafting with the Valiant device, using enrollment criteria similar to VALOR. The outcomes of VALOR II 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.<sup>22</sup> Three-year follow-up evaluations were available for 127 (65.5%) patients in the 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 ( $p < .001$ ). 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 U.S. Food Drug Administration based on results of the trial reported by Matsumara et al (2008).<sup>23</sup> 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 ( $p < .01$ ) and higher Society of Vascular Surgery/International Society of Cardiovascular Surgery risk score ( $p = .03$ ). The 30-day survival rate for the endovascular group (98.1%) was noninferior to the control group (94.3%;  $p < .01$ ). 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;  $p < .01$ ). 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.<sup>24</sup> 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. The 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 ( $p=.88$ ). Kaplan-Meier estimates for freedom from severe morbidity were 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  $p<.001$ ). 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. Patients treated with TEVAR have a higher rate of long-term complications, primarily from endoleaks, and a higher reintervention rate. These 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.

### **Uncomplicated Type B Aortic Dissections**

#### **Clinical Context and Therapy Purpose**

The purpose of endovascular repair is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with uncomplicated type B (descending) thoracic aortic dissections.

The question addressed in this evidence review is: Does the use of endovascular repair improve the net health outcome in patients with uncomplicated type B (descending) thoracic aortic dissections?

The following PICO was used to select literature to inform this review.

#### ***Populations***

The relevant population of interest are individuals with uncomplicated type B (descending) thoracic aortic dissections.

#### ***Interventions***

The therapy being considered is endovascular repair.

#### ***Comparators***

The following practice is currently being used to treat uncomplicated type B (descending) thoracic aortic dissections: open surgical repair or medical management.

#### ***Outcomes***

The general outcomes of interest are OS, morbid events, treatment-related mortality, and treatment-related morbidity. Follow-up of at least 5 years is of interest to monitor outcomes.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Acute, Uncomplicated Type B Aortic Dissections

Hossack et al (2020) published a systematic review of 6 studies evaluating patients with acute or subacute uncomplicated type B aortic dissection who were treated with TEVAR or best medical therapy (N=14,706).<sup>25</sup> There were 2 RCTs (Brunkwall et al 2014 and Nienaber et al 2009) and 4 observational studies included; the RCT by Brunkwall et al is summarized in more detail in the section below, and 1-year and 5-year follow up of patients from the RCT by Nienaber et al (which included patients presenting >2 weeks after dissection) are presented in the section focused on chronic, uncomplicated type B aortic dissections. The primary outcomes of the review were early mortality and re-intervention, late all-cause and aorta-related mortality, and re-intervention. The authors defined early mortality as occurring within 30 days of the procedure, including in-hospital deaths; the time frame for "late" outcomes was not specified. Results demonstrated that early mortality occurred in a similar proportion of patients in the TEVAR and best medical therapy groups (6.3% and 7.4%, respectively; risk difference, 0.01; 95% CI, -0.01 to 0.02; p=.46). There was also no difference in rates of early intervention between TEVAR and best medical therapy groups (0.7% and 2.4%, respectively; risk difference, 0.02; 95% CI, -0.01 to -0.04; p=.19). The early surgical intervention rate in both the medical and TEVAR groups was 0%. Late all-cause mortality was significantly improved with TEVAR (hazard ratio, 1.54; 95% CI, 1.27 to 1.86), as was aorta-related mortality (hazard ratio, 2.7; 95% CI, 1.49 to 4.94). Data for late reintervention were not available. Given the limited number and quality of available studies, the authors concluded that it remains uncertain whether TEVAR is beneficial in the treatment of acute, uncomplicated type B aortic dissection.

### Randomized Controlled Trials

One RCT, 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 (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).<sup>26</sup> A summary of key trial characteristics is presented in Table 2. 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 endpoint calculations as failures. The trial's primary endpoint 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. A summary of key trial results is presented in Table 3. At 1 year, 15 (50.0%) of the 30 TEVAR patients had at least 1 endpoint event, and all 31 best medical therapy patients had at least 1 endpoint event (p<.001). In the control group, 30 patients had 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. Study relevance, conduct, and design limitations are summarized in Tables 4 and 5.

**Table 2. Summary of Key Randomized Controlled Trial Characteristics**

Study; Trial	Countries	Sites	Dates	Participants	Interventions
Brunkwall et al (2014) <sup>26</sup>	Europe	17	Dec 2008 to Dec 2010	Patients presenting with an acute uncomplicated type B dissection and without evidence of connective tissue disease within 14 days of onset of symptom.	Endoluminal repair using a Gore TAG device (n=30) Best medical treatment (n=31)

**Table 3. Summary of Key Randomized Controlled Trial Results**

Study	One of the following at 1 year: false lumen thrombosis, aortic dilation, and aortic rupture	False lumen thrombosis at 1 year	Aortic dilation at 1 year	Aortic rupture at 1 year	Mortality at 30 days
Brunkwall et al (2014) <sup>26</sup>					
Endoluminal repair using a Gore TAG device, n (%)	15 (50%)	13 (43%)	11 (37%)	0 (0%)	0 (0%)
Best medical treatment, n (%)	31 (100%)	30 (97%)	14 (45%)	0 (0%)	0 (0%)
p-value	.001	<.001	.500	NA	NA

NA: not available.

**Table 4. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-up <sup>e</sup>
Brunkwall et al (2014) <sup>26</sup>	5. All study sites were in Europe	5. All centers were experienced in both medical treatment and endovascular repair of patients with dissection.	5. All centers were experienced in both medical treatment and endovascular repair of patients with dissection.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

<sup>b</sup> Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

<sup>d</sup> Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

**Table 5. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Brunkwall et al (2014) <sup>26</sup>				7. Challenges in obtaining quality follow-up imaging resulting in 14 failures	4. Not powered for mortality outcomes	

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
due to imaging issues/dropouts.						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

<sup>b</sup> Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

<sup>d</sup> Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

<sup>f</sup> Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

### Retrospective Studies

Xiang et al (2021) published a retrospective study comparing outcomes in a matched population of patients with acute, uncomplicated type B aortic dissection who received TEVAR (n=145) or best medical therapy (n=145).<sup>27</sup> Results demonstrated that at 30 days, there were similar rates of mortality in the TEVAR and best medical therapy group (1 vs. 3 patients; p=.622), but significantly increased rates of adverse events with TEVAR (17 patients [11.7%] vs. 4 patients [2.8%]; p=.003). At 1, 3, and 5 years, freedom from all-cause death was significantly improved with TEVAR (97.2%, 96.4%, and 91.9%, respectively) versus best medical therapy (94.2%, 88.5%, and 82.2%, respectively) (overall p=.028); similar trends favoring TEVAR were also seen for freedom from aortic-related death (overall p=.044). The cumulative incidence of rupture at 1, 3, and 5 years was significantly reduced with TEVAR (2.1%, 2.1%, and 5.1%, respectively) compared to best medical therapy (5.7%, 9.7%, and 13.7%, respectively; overall p=.024). Endoleaks with TEVAR occurred in 2.1%, 3.6%, and 6% of patients who received TEVAR at 1, 3, and 5 years, respectively.

### Section Summary: Acute, Uncomplicated Type B Aortic Dissections

In a systematic review, the risk of late all-cause mortality was reduced with TEVAR versus best medical management; however, the authors did not quantify the time frame for late outcomes. Additional limitations include analyses of a few and mostly lower-quality studies, and the inclusion of data from patients with chronic, stable thoracic aorta dissections in the analyses; these limitations likely contributed to the authors conclusion that noted that it remains uncertain whether TEVAR is beneficial in the treatment of acute, uncomplicated type B aortic dissection. 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. A retrospective study found increased rates of early adverse events with TEVAR compared to best medical management; however, survival rates were significantly improved with TEVAR versus best medical therapy at 1, 3, and 5 years (97.2%, 96.4%, and 91.9%, respectively vs. 94.2%, 88.5%, and 82.2%, respectively), and aortic rupture rates were significantly reduced with TEVAR (2.1%, 2.1%, and 5.1%, respectively vs. 5.7%, 9.7%, and 13.7%, respectively).

### Chronic, Uncomplicated 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

Boufi et al (2019) conducted a systematic review and meta-analysis to compare early outcomes, midterm or long-term survival, and reintervention rates after chronic type B aortic dissection repair with either open or endovascular intervention.<sup>28</sup> A total of 39 studies were included; 2 of these (N=195) were comparative. Most studies were retrospective and conducted at single centers. In the comparative studies, cumulative all-cause early mortality was significantly lower with endovascular repair versus open surgery (odds ratio [OR], 4.13; 95% CI, 1.10 to 15.4;  $p=.035$ ). Adverse neurologic events were significantly higher with open surgery. Survival analysis did not indicate a benefit of 1 technique over the other at 1 year (OR, 0.73; 95% CI, 0.34 to 1.55,  $p=.41$ ) or 3 years (OR, 1.19; 95% CI, 0.42 to 3.32,  $p=.73$ ). Compared with open surgery, endovascular repair significantly increased reintervention risk (OR, 0.34; 95% CI, 0.16 to 0.69;  $p=.003$ ). Data from noncomparative studies showed lower cumulative all-cause early mortality with endovascular repair (2%; 95% CI, 0% to 0.03% vs. 9.3%; 95% CI, 0.07% to 0.12%), but 1-year and 3-year survival rates were similar for the 2 procedures.

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.<sup>29</sup> 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).<sup>30</sup> 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 endpoint (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 ( $p=.16$ ). In addition, the aorta-related mortality rate did not differ (5.7% vs. 3.0%, respectively;  $p=.42$ ). There were 2 cases of ischemic spinal cord injury, 1 in each group. Seven (10.6%) patients in the medical group crossed over to the stent graft group, and 1 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;  $p<.001$ ), 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).<sup>31</sup> 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 to 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;  $p=.13$ ). For the combined endpoint of disease progression (aorta-specific death, crossover/conversion, secondary procedures) and aorta-specific events at 5 years of follow-up, freedom from the combined endpoint 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 beginning 2 years post procedure. 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. In a systematic review of mostly noncomparative studies, cumulative all-cause early mortality was lower with TEVAR compared with open surgery, but 1-year and 3-year survival rates were similar between the 2 procedures.

### Complicated Type B Aortic Dissections

#### Clinical Context and Therapy Purpose

The purpose of endovascular repair is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with complicated type B (descending) thoracic aortic dissections.

The question addressed in this evidence review is: Does the use of endovascular repair improve the net health outcome in patients with complicated type B (descending) thoracic aortic dissections?

The following PICO was used to select literature to inform this review.

#### *Populations*

The relevant population of interest are individuals with complicated type B (descending) thoracic aortic dissections.

#### *Interventions*

The therapy being considered is endovascular repair.

#### *Comparators*

The following practice is currently being used to treat complicated type B (descending) thoracic aortic dissections: open surgical repair or medical management.

#### *Outcomes*

The general outcomes of interest are OS, morbid events, treatment-related mortality, and treatment-related morbidity. Follow-up of at least 5 years is of interest to monitor outcomes.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

#### Systematic Reviews

Wilson-Smith et al (2021) reported on the results of a systematic review that assessed long-term survival and freedom from reintervention in patients with acute complicated type B aortic dissection who received treatment with TEVAR (N=2,565).<sup>32</sup> "Complicated" dissection was defined as aortic rupture and/or the presence of organ malperfusion syndromes. The rate of actutimes survival at 2, 4,

6, and 10 years was 87.5%, 83.2%, 78.5%, and 69.7%, respectively, and rate of freedom from all secondary reintervention at 2, 4, 6, 8, and 10 years was 74.7%, 69.1%, 65.7%, 63.9%, and 60.9%, respectively. The most commonly reported adverse events in the early postoperative period were reoperations (n=401 [72%]), spinal cord ischemia (n=53 [6%]), stroke (n=70 [59%]), and endoleak (n=110 [50%]). Direct comparisons between treatment groups were not reported, which limits conclusions that may be drawn.

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.<sup>12</sup> "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 the 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) reported the findings of 1129 consecutive patients with acute, type B aortic dissections enrolled in the International Registry of Acute Aortic Dissection (IRAD) between 1995 and 2012 who received medical (n=853 [75.6%]) or TEVAR (n=276 [24.4%]) therapy.<sup>33</sup> The choice of medical therapy or TEVAR was based on presenting illness and resulted in a subsequent lack of balance in baseline characteristics between groups. At baseline, TEVAR patients were more likely than medical therapy patients to present with pulse deficit (28.3% vs. 13.4%; p<.001), lower extremity ischemia (16.8% vs. 3.6%; p<.001), complicated acute aortic dissection (defined as shock, periaortic hematoma, signs of malperfusion, stroke, spinal cord ischemia, mesenteric ischemia, and/or renal failure) (61.7% vs. 37.2%), and characterize their pain as the "worst ever" (27.5% vs. 15.7%; p<.001) or "severe or worst ever" (97.4% vs. 92.3%; p=.010). Because patients were not randomly assigned to the 2 treatment groups, the authors reported a comparative analysis using a propensity model. Results demonstrated that despite the initially higher risk profile of patients who received TEVAR, the 5-year Kaplan-Meier mortality estimates were significantly lower for patients managed with TEVAR versus medical therapy (15.5% vs. 29.0%; p=.018); 1-year mortality rates were similar between groups (8.1% vs. 9.8%, respectively; p=.604). Limitations of this study should be considered when interpreting the results. First, the selection of patients from centers specializing in the management of aortic disease may not reflect patient management in non-specialized settings. Also, the retrospective nature of the study is subject to referral bias, and the evaluation of complications and cause of death may vary depending on differences in data interpretation. Collectively, the limitations of this study introduce uncertainty about its results.

### Section Summary: Acute, Complicated Type B Aortic Dissections

For patients with acute, complicated type B aortic dissections, there is limited evidence from 2 systematic reviews of observational studies and case series and a propensity-matched study, the latter of which reported similar survival rates at 1 year with TEVAR versus medical therapy, but a significant 5-year survival advantage for patients treated with TEVAR. In the propensity-matched study, the choice of medical therapy or TEVAR was based on presenting illness and resulted in a



subsequent lack of balance in baseline characteristics between groups. Furthermore, patients were selected from centers specializing in the management of aortic disease, and data were collected retrospectively. Together, these limitations introduce uncertainty about the results of this study. In one of the systematic reviews, rates of survival and freedom from all secondary reinterventions at 10 years were 69.7% and 60.9%, respectively.

## **Tears and Rupture of the Descending Aorta**

### **Clinical Context and Therapy Purpose**

The purpose of endovascular repair is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with traumatic descending aortic tears or rupture. The question addressed in this evidence review is: Does the use of endovascular repair improve the net health outcome in patients with traumatic descending aortic tears or rupture?

The following PICO was used to select literature to inform this review.

### ***Populations***

The relevant population of interest are individuals with traumatic descending aortic tears or rupture.

### ***Interventions***

The therapy being considered is endovascular repair.

### ***Comparators***

The following practice is currently being used to treat traumatic descending aortic tears or rupture: open surgical repair.

### ***Outcomes***

The general outcomes of interest are OS, morbid events, treatment-related mortality, and treatment-related morbidity. Follow-up of at least 5 years is of interest to monitor outcomes.

## **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

## **Review of Evidence**

### **Systematic Reviews**

A Cochrane review by Pang et al(2019) 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.<sup>34</sup> Reviewers did not identify any RCTs meeting their selection criteria.

### **Ruptured Descending Thoracic Aortic Aneurysm**

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.<sup>35</sup> The 30-day mortality was 19% for patients treated with endovascular repair and 33% for patients treated with open repair (p=.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.<sup>36</sup> 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%, and 46%, respectively ;  $p < .01$ ). 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.<sup>37</sup> 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 to 2004 to 43% in 2011 to 2012 ( $p < .001$ ). 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%;  $p < .001$ ). In adjusted analysis, the open repair was associated with 2-fold higher mortality than TEVAR (OR, 2.0; 95% CI, 1.7 to 2.5).

Additional nonrandomized comparative studies using trauma registry data have found lower short-term mortality, complications, and hospital or intensive care unit length of stay with endovascular repair compared to open surgery.<sup>38,39,40</sup> These studies are all limited by their observational design and noncomparability of treatment groups.

### **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**

#### **Clinical Context and Therapy Purpose**

The purpose of endovascular repair is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with ascending aortic disorders.

The question addressed in this evidence review is: Does the use of endovascular repair improve the net health outcome in patients with ascending aortic disorders?

The following PICO was used to select literature to inform this review.

#### ***Populations***

The relevant population of interest are individuals with ascending aortic disorders.

#### ***Interventions***

The therapy being considered is endovascular repair.

#### ***Comparators***

The following practice is currently being used to treat ascending aortic disorders: open surgical repair.

### **Outcomes**

The general outcomes of interest are OS, morbid events, treatment-related mortality, and treatment-related morbidity. Follow-up of at least 5 years is of interest to monitor outcomes.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### **Case Series**

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.<sup>41</sup> 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).<sup>42</sup> 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).<sup>43</sup> Appoo et al (2015) reported on imaging-related outcomes for 16 patients who underwent TEVAR for aortic arch or ascending aorta.<sup>44</sup>

#### **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) TAAs who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are OS, 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 an improvement in the net health outcome.

For individuals who have uncomplicated type B (descending) thoracic aortic dissections who receive endovascular repair, the evidence includes RCTs, systematic reviews, and retrospective cohort studies with longer follow up. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. For acute, uncomplicated type B dissections, a systematic review demonstrated that the risk of late all-cause mortality was reduced with TEVAR versus best medical management; however, the authors did not quantify the time frame for late outcomes. 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. In addition, a retrospective study that evaluated a matched population of patients found increased rates of early adverse events with TEVAR compared to best medical

management; however, survival rates were significantly improved with TEVAR versus best medical therapy at 1, 3, and 5 years, and aortic rupture rates were significantly reduced with TEVAR at these time points as well. For chronic, uncomplicated 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. In a systematic review of mostly noncomparative studies, cumulative all-cause early mortality was lower with TEVAR compared with open surgery, but 1-year and 3-year survival rates were similar between the 2 procedures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have complicated type B (descending) thoracic aortic dissections who receive endovascular repair, the evidence includes systematic reviews and nonrandomized comparative studies. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. Short- and intermediate-term results from a systematic review of observational studies that compared TEVAR with open surgery have suggested a benefit for TEVAR in complicated (organ or limb ischemia or rupture) type B dissection. In another systematic review, the rate of survival and freedom from all secondary reinterventions at 10 years was 69.7% and 60.9%, respectively. In a propensity-matched study, an early survival advantage was demonstrated for patients treated with TEVAR compared with best medical management. However, the choice of medical management or TEVAR was based on presenting illness; therefore, the groups were not balanced at baseline, which raises uncertainty about the results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 OS, 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 that the technology results in an improvement in the net health outcome.

For individuals who have ascending aortic disorders who receive endovascular repair, the evidence includes small case series. Relevant outcomes are OS, 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 that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **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 aortic repair (TEVAR) in complicated type B aortic dissections and, in certain cases, in traumatic thoracic aortic injury.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American College of Cardiology Foundation

In 2010, the American College of Cardiology Foundation, American Heart Association, and 8 other medical specialty societies published joint guidelines on the diagnosis and management of descending thoracic and thoracoabdominal aortic aneurysms.<sup>45</sup> The guidelines offered the following recommendations (Table 6).

**Table 6. Joint Guidelines on Descending Thoracic and Thoracoabdominal Aortic Aneurysms**

Recommendation	COR	LOE
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	I	B
For patients with degenerative or traumatic aneurysms of the descending thoracic aorta exceeding 5.5 cm, saccular aneurysms, or postoperative pseudoaneurysms, endovascular stent grafting should be strongly considered when feasible	I	B
For patients with thoracoabdominal aneurysms, in whom endovascular stent graft options are limited and surgical morbidity is elevated, elective surgery is recommended if the aortic diameter exceeds 6.0 cm, or less if a connective tissue disorder such as Marfan or Loeys-Dietz syndrome is present	I	C
For patients with thoracoabdominal aneurysms and with end-organ ischemia or significant stenosis from atherosclerotic visceral artery disease, an additional revascularization procedure is recommended	I	B

COR: class of recommendation; LOE: level of evidence.

At the time of publication of this guideline in 2010, endovascular stent grafts were approved by the U.S. Food and Drug Administration only for aneurysms involving the descending thoracic aorta; therefore, other indications such as acute and chronic type B aortic dissection, intramural hematoma, penetrating aortic ulcer, acute traumatic aortic transection, and pseudoaneurysms, were considered "off label." These guidelines have not been updated since 2010.

### National Institute for Health and Care Excellence

In 2005, NICE published guidelines on endovascular stent-graft placement in thoracic aortic aneurysms (TAAs) and dissections.<sup>46</sup> The guideline stated: "Current evidence on the safety and efficacy of endovascular stent-graft placement in thoracic aortic aneurysms and dissections indicates that it is a suitable alternative to surgery in appropriately selected patients, provided that the normal arrangements are in place for consent, audit and clinical governance." This recommendation was based on a systematic review of 27 case series and 2 comparative observational studies.

### Society for Vascular Surgery

In 2021, the Society for Vascular Surgery published guidelines on TEVAR for descending TAAs.<sup>16</sup> The guideline included the following recommendations (Table 7).

**Table 7. Society for Vascular Surgery Guidelines on Thoracic Endovascular Aortic Repair for Descending Aortic Aneurysms**

Recommendation	LOR	QOE
In patients who could undergo either technique (open repair vs. TEVAR) (within the criteria of the device's instructions for use), we recommend TEVAR as the preferred approach to treat elective DTA aneurysms, given its reduced morbidity and length of stay as well as short-term mortality	1	A

Recommendation	LOR	QOE
We recommend TEVAR in asymptomatic patients with a descending TAA when the maximum aneurysm diameter exceeds 5.5 cm in “low-risk” patients with favorable aortic anatomy	1	B
We suggest using higher aortic diameter thresholds for TEVAR in patients deemed to have a particularly high risk of death, renal failure, or paraplegia from the procedure, where the benefit of treatment is lower than the risk posed by the natural history of the TAA	2	C
We recommend TEVAR in patients with IMH or penetrating aortic ulcer who have persistent symptoms or complications or show evidence of disease progression on follow-up imaging after a period of hypertension control	1	B
We suggest TEVAR in selected cases of asymptomatic penetrating aortic ulcer in patients who have at-risk characteristics for growth or rupture	2	B
We suggest TEVAR for symptomatic mycotic/infected TAA as a temporizing measure, but data demonstrating long-term benefit are lacking	2	C
We recommend TEVAR over open repair for the treatment of ruptured DTA when anatomically feasible	1	B
We recommend contrast-enhanced computed tomography scanning at 1 month and 12 months after TEVAR and then yearly for life, with consideration of more frequent imaging if an endoleak or other abnormality of concern is detected at 1 month	1	B

DTA: descending thoracic aorta; IMH: intramural hematoma; LOR: level of recommendation; QOE: quality of evidence; TAA: thoracic aortic aneurysm; TEVAR: thoracic endovascular aortic repair

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

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.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 8.

**Table 8. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02622542	A Randomized Controlled Comparative Study on Effectiveness of Endovascular Repair Versus Best Medical Therapy for Acute Uncomplicated Type B Aortic Dissection	436	Jun 2026
NCT02735720	The Cardiovascular Remodeling Following Endovascular Aortic Repair (CORE) Study	24	Dec 2022
<i>Unpublished</i>			
NCT02010892	Effective Treatments for Thoracic Aortic Aneurysms (ETTAA Study): A Prospective Cohort Study	2200	Jul 2019

NCT: national clinical trial.

## References

1. Clouse WD, Hallett JW, Schaff HV, et al. Improved prognosis of thoracic aortic aneurysms: a population-based study. *JAMA*. Dec 09 1998; 280(22): 1926-9. PMID 9851478
2. Davies RR, Goldstein LJ, Coady MA, et al. Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size. *Ann Thorac Surg*. Jan 2002; 73(1): 17-27; discussion 27-8. PMID 11834007
3. Coady MA, Rizzo JA, Hammond GL, et al. Surgical intervention criteria for thoracic aortic aneurysms: a study of growth rates and complications. *Ann Thorac Surg*. Jun 1999; 67(6): 1922-6; discussion 1953-8. PMID 10391339
4. Rectenwald JE, Huber TS, Martin TD, et al. Functional outcome after thoracoabdominal aortic aneurysm repair. *J Vasc Surg*. Apr 2002; 35(4): 640-7. PMID 11932656

5. Estrera AL, Miller CC, Huynh TT, et al. Neurologic outcome after thoracic and thoracoabdominal aortic aneurysm repair. *Ann Thorac Surg.* Oct 2001; 72(4): 1225-30; discussion 1230-1. PMID 11603441
6. Huynh TT, Miller CC, Estrera AL, et al. Thoracoabdominal and descending thoracic aortic aneurysm surgery in patients aged 79 years or older. *J Vasc Surg.* Sep 2002; 36(3): 469-75. PMID 12218969
7. Estrera AL, Rubenstein FS, Miller CC, et al. Descending thoracic aortic aneurysm: surgical approach and treatment using the adjuncts cerebrospinal fluid drainage and distal aortic perfusion. *Ann Thorac Surg.* Aug 2001; 72(2): 481-6. PMID 11515886
8. Safi HJ, Miller CC, Subramaniam MH, et al. Thoracic and thoracoabdominal aortic aneurysm repair using cardiopulmonary bypass, profound hypothermia, and circulatory arrest via left side of the chest incision. *J Vasc Surg.* Oct 1998; 28(4): 591-8. PMID 9786251
9. Safi HJ, Subramaniam MH, Miller CC, et al. Progress in the management of type I thoracoabdominal and descending thoracic aortic aneurysms. *Ann Vasc Surg.* Sep 1999; 13(5): 457-62. PMID 10466987
10. van Dongen EP, Schepens MA, Morshuis WJ, et al. Thoracic and thoracoabdominal aortic aneurysm repair: use of evoked potential monitoring in 118 patients. *J Vasc Surg.* Dec 2001; 34(6): 1035-40. PMID 11743557
11. Webb TH, Williams GM. Thoracoabdominal aneurysm repair. *Cardiovasc Surg.* Oct 1999; 7(6): 573-85. PMID 10519663
12. MacGillivray TE, Gleason TG, Patel HJ, et al. The Society of Thoracic Surgeons/American Association for Thoracic Surgery clinical practice guidelines on the management of type B aortic dissection. *J Thorac Cardiovasc Surg.* Apr 2022; 163(4): 1231-1249. PMID 35090765
13. Lombardi JV, Gleason TG, Panneton JM, et al. STABLE II clinical trial on endovascular treatment of acute, complicated type B aortic dissection with a composite device design. *J Vasc Surg.* Apr 2020; 71(4): 1077-1087.e2. PMID 31477479
14. Isselbacher EM, Preventza O, Hamilton Black lii J, et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* Dec 13 2022; 80(24): e223-e393. PMID 36334952
15. Food and Drug Administration Summary of Safety and Effectiveness. Valiant Thoracic Stent Graft with the Captivia Delivery System. 2014; [http://www.accessdata.fda.gov/cdrh\\_docs/pdf10/P100040S012b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100040S012b.pdf). Accessed April 4, 2023.
16. Food and Drug Administration. Approval Order: Medtronic PMA P100040. 2018; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf5/P050023S058A.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050023S058A.pdf). Accessed April 4, 2023.
17. Food and Drug Administration. Medtronic Announces Voluntary Recall of Unused Valiant Navion Thoracic Stent Graft System. Published February 23, 2021. [https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/medtronic-announces-voluntary-recall-unused-valiant-naviontm-thoracic-stent-graft-system#:~:text=Medtronic%20plc%20\(NYSE%3AMD\),the%20device%20until%20further%20notice](https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/medtronic-announces-voluntary-recall-unused-valiant-naviontm-thoracic-stent-graft-system#:~:text=Medtronic%20plc%20(NYSE%3AMD),the%20device%20until%20further%20notice). Accessed April 4, 2023.
18. Upchurch GR, Escobar GA, Azizzadeh A, et al. Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms. *J Vasc Surg.* Jan 2021; 73(1S): 55S-83S. PMID 32628988
19. Abraha I, Romagnoli C, Montedori A, et al. Thoracic stent graft versus surgery for thoracic aneurysm. *Cochrane Database Syst Rev.* Jun 06 2016; 2016(6): CD006796. PMID 27265222
20. Makaroun MS, Dillavou ED, Kee ST, et al. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. *J Vasc Surg.* Jan 2005; 41(1): 1-9. PMID 15696036
21. Makaroun MS, Dillavou ED, Wheatley GH, et al. Five-year results of endovascular treatment with the Gore TAG device compared with open repair of thoracic aortic aneurysms. *J Vasc Surg.* May 2008; 47(5): 912-8. PMID 18353605

22. Fairman RM, Criado F, Farber M, et al. Pivotal results of the Medtronic Vascular Talent Thoracic Stent Graft System: the VALOR trial. *J Vasc Surg.* Sep 2008; 48(3): 546-54. PMID 18572352
23. Fairman RM, Tucheck JM, Lee WA, et al. Pivotal results for the Medtronic Valiant Thoracic Stent Graft System in the VALOR II trial. *J Vasc Surg.* Nov 2012; 56(5): 1222-31.e1. PMID 22832267
24. Matsumoto AH, Angle JF, Secic M, et al. Secondary procedures following thoracic aortic stent grafting in the first 3 years of the VALOR test and VALOR II trials. *J Vasc Interv Radiol.* May 2014; 25(5): 685-692.e5. PMID 24529546
25. Matsumura JS, Cambria RP, Dake MD, et al. International controlled clinical trial of thoracic endovascular aneurysm repair with the Zenith TX2 endovascular graft: 1-year results. *J Vasc Surg.* Feb 2008; 47(2): 247-257; discussion 257. PMID 18241743
26. Matsumura JS, Melissano G, Cambria RP, et al. Five-year results of thoracic endovascular aortic repair with the Zenith TX2. *J Vasc Surg.* Jul 2014; 60(1): 1-10. PMID 24636714
27. Hossack M, Patel S, Gambardella I, et al. Endovascular vs. Medical Management for Uncomplicated Acute and Sub-acute Type B Aortic Dissection: A Meta-analysis. *Eur J Vasc Endovasc Surg.* May 2020; 59(5): 794-807. PMID 31899101
28. Brunkwall J, Kasprzak P, Verhoeven E, et al. Endovascular repair of acute uncomplicated aortic type B dissection promotes aortic remodelling: 1 year results of the ADSORB trial. *Eur J Vasc Endovasc Surg.* Sep 2014; 48(3): 285-91. PMID 24962744
29. Iannuzzi JC, Stapleton SM, Bababekov YJ, et al. Favorable impact of thoracic endovascular aortic repair on survival of patients with acute uncomplicated type B aortic dissection. *J Vasc Surg.* Dec 2018; 68(6): 1649-1655. PMID 29914833
30. Xiang D, Kan X, Liang H, et al. Comparison of mid-term outcomes of endovascular repair and medical management in patients with acute uncomplicated type B aortic dissection. *J Thorac Cardiovasc Surg.* Jul 2021; 162(1): 26-36.e1. PMID 31982125
31. Boufi M, Patterson BO, Loundou AD, et al. Endovascular Versus Open Repair for Chronic Type B Dissection Treatment: A Meta-Analysis. *Ann Thorac Surg.* May 2019; 107(5): 1559-1570. PMID 30481516
32. Thrumurthy SG, Karthikesalingam A, Patterson BO, et al. A systematic review of mid-term outcomes of thoracic endovascular repair (TEVAR) of chronic type B aortic dissection. *Eur J Vasc Endovasc Surg.* Nov 2011; 42(5): 632-47. PMID 21880515
33. Nienaber CA, Kische S, Akin I, et al. Strategies for subacute/chronic type B aortic dissection: the Investigation Of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial 1-year outcome. *J Thorac Cardiovasc Surg.* Dec 2010; 140(6 Suppl): S101-8; discussion S142-S146. PMID 21092774
34. Nienaber CA, Kische S, Rousseau H, et al. Endovascular repair of type B aortic dissection: long-term results of the randomized investigation of stent grafts in aortic dissection trial. *Circ Cardiovasc Interv.* Aug 2013; 6(4): 407-16. PMID 23922146
35. Leshnower BG, Szeto WY, Pochettino A, et al. Thoracic endografting reduces morbidity and remodels the thoracic aorta in DeBakey III aneurysms. *Ann Thorac Surg.* Mar 2013; 95(3): 914-21. PMID 23245448
36. Andersen ND, Keenan JE, Ganapathi AM, et al. Current management and outcome of chronic type B aortic dissection: results with open and endovascular repair since the advent of thoracic endografting. *Ann Cardiothorac Surg.* May 2014; 3(3): 264-74. PMID 24967165
37. van Bogerijen GH, Patel HJ, Williams DM, et al. Propensity adjusted analysis of open and endovascular thoracic aortic repair for chronic type B dissection: a twenty-year evaluation. *Ann Thorac Surg.* Apr 2015; 99(4): 1260-6. PMID 25686670
38. Wilson-Smith AR, Muston B, Kamalanathan H, et al. Endovascular repair of acute complicated type B aortic dissection-systematic review and meta-analysis of long-term survival and reintervention. *Ann Cardiothorac Surg.* Nov 2021; 10(6): 723-730. PMID 34926176
39. Moulakakis KG, Mylonas SN, Dalainas I, et al. Management of complicated and uncomplicated acute type B dissection. A systematic review and meta-analysis. *Ann Cardiothorac Surg.* May 2014; 3(3): 234-46. PMID 24967162



40. Fattori R, Montgomery D, Lovato L, et al. Survival after endovascular therapy in patients with type B aortic dissection: a report from the International Registry of Acute Aortic Dissection (IRAD). *JACC Cardiovasc Interv.* Aug 2013; 6(8): 876-82. PMID 23968705
41. Gennai S, Leone N, Mezzetto L, et al. Systematic review and meta-analysis of long-term reintervention following thoracic endovascular repair for blunt traumatic aortic injury. *J Vasc Surg.* Aug 2023; 78(2): 540-547.e4. PMID 36754248
42. Harky A, Bleetman D, Chan JSK, et al. A systematic review and meta-analysis of endovascular versus open surgical repair for the traumatic ruptured thoracic aorta. *J Vasc Surg.* Jan 2020; 71(1): 270-282. PMID 31327611
43. Lee WA, Matsumura JS, Mitchell RS, et al. Endovascular repair of traumatic thoracic aortic injury: clinical practice guidelines of the Society for Vascular Surgery. *J Vasc Surg.* Jan 2011; 53(1): 187-92. PMID 20974523
44. Scalea TM, Feliciano DV, DuBose JJ, et al. Blunt Thoracic Aortic Injury: Endovascular Repair Is Now the Standard. *J Am Coll Surg.* Apr 2019; 228(4): 605-610. PMID 30630086
45. Elkbuli A, Dowd B, Spano PJ, et al. Thoracic Endovascular Aortic Repair Versus Open Repair: Analysis of the National Trauma Data Bank. *J Surg Res.* Jan 2020; 245: 179-182. PMID 31421360
46. Yamaguchi T, Nakai M, Sumita Y, et al. Editor's Choice - Endovascular Repair Versus Surgical Repair for Japanese Patients With Ruptured Thoracic and Abdominal Aortic Aneurysms: A Nationwide Study. *Eur J Vasc Endovasc Surg.* Jun 2019; 57(6): 779-786. PMID 30837104
47. De Freitas S, Rossi MJ, Abramowitz SD, et al. Systematic review and meta-analysis of endovascular interventions for Stanford type A aortic dissection. *J Vasc Surg.* Nov 2021; 74(5): 1721-1731.e4. PMID 33592292
48. Vallabhajosyula P, Gottret JP, Bavaria JE, et al. Endovascular repair of the ascending aorta in patients at high risk for open repair. *J Thorac Cardiovasc Surg.* Feb 2015; 149(2 Suppl): S144-50. PMID 25218530
49. Roselli EE, Idrees J, Greenberg RK, et al. Endovascular stent grafting for ascending aorta repair in high-risk patients. *J Thorac Cardiovasc Surg.* Jan 2015; 149(1): 144-51. PMID 25312226
50. Appoo JJ, Herget EJ, Pozeg ZI, et al. Midterm results of endovascular stent grafts in the proximal aortic arch (zone 0): an imaging perspective. *Can J Cardiol.* Jun 2015; 31(6): 731-7. PMID 25882336
51. Hiratzka LF, Bakris GL, Beckman JA, et al. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the diagnosis and management of patients with thoracic aortic disease. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. *J Am Coll Cardiol.* Apr 06 2010; 55(14): e27-e129. PMID 20359588
52. National Institute for Health and Care Excellence. Endovascular stent-graft placement in thoracic aortic aneurysms and dissections. June 22, 2005. Accessed April 4, 2023. <https://www.nice.org.uk/guidance/ipg127>

## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Reason for endovascular stent graft
  - Name of endovascular stent graft used
  - Imaging report(s) of thoracic aorta disorder

**Post Service (in addition to the above, please include the following):**

- Procedure report

**Coding**

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	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 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(s) delayed after endovascular repair of descending thoracic aorta
	33889	Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral
	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 left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation

Type	Code	Description
	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(s) (delayed) after endovascular repair of descending thoracic aorta, as needed, to level of celiac origin, radiological supervision and interpretation
HCPCS	None	

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
09/27/2013	BCBSA Medical Policy adoption
09/30/2014	Policy revision without position change
07/01/2016	Policy revision without position change
07/01/2017	Policy revision without position change
07/01/2018	Policy revision without position change
07/01/2019	Policy revision without position change
07/01/2020	Annual review. No change to policy statement. Literature review updated.
07/01/2021	Annual review. No change to policy statement. Policy guidelines and literature review updated.
08/01/2022	Annual review. No change to policy statement. Literature review updated.
08/01/2023	Annual review. No change to policy statement.
12/01/2023	No change to policy statement. Policy guidelines and literature review updated

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Endovascular Stent Grafts for Disorders of the Thoracic Aorta 7.01.86</b></p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) may be considered <b>medically necessary</b> for the treatment of <b>any</b> of the following:                             <ul style="list-style-type: none"> <li>A. Descending thoracic aortic aneurysms used according to FDA-approved specifications (see Policy Guidelines section)</li> <li>B. Acute, complicated (organ or limb ischemia or rupture) type B thoracic aortic dissection</li> <li>C. Traumatic descending aortic tears or rupture</li> </ul> </li>   <li>II. Endovascular stent grafts are considered <b>investigational</b> for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated aortic dissection.</li>   <li>III. Endovascular stent grafts are considered <b>investigational</b> for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms.</li> </ul>	<p><b>Endovascular Stent Grafts for Disorders of the Thoracic Aorta 7.01.86</b></p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) may be considered <b>medically necessary</b> for the treatment of <b>any</b> of the following:                             <ul style="list-style-type: none"> <li>A. Descending thoracic aortic aneurysms used according to FDA-approved specifications (see Policy Guidelines section)</li> <li>B. Acute, complicated (organ or limb ischemia or rupture) type B thoracic aortic dissection</li> <li>C. Traumatic descending aortic tears or rupture</li> </ul> </li>   <li>II. Endovascular stent grafts are considered <b>investigational</b> for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated aortic dissection.</li>   <li>III. Endovascular stent grafts are considered <b>investigational</b> for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms.</li> </ul>