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Endovascular Stent Grafts for Disorders of the Thoracic Aorta

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Related Policies (if applicable)
None

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Coverage

Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) and used according to their FDA-approved specifications **may be considered medically necessary** for the following conditions:

- Descending thoracic aortic aneurysms, OR
- Acute, complicated (organ or limb ischemia or rupture) type B thoracic aortic dissection, OR
- Traumatic descending aortic tears or rupture.

Endovascular stent grafts **are considered experimental, investigational and/or unproven** for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated aortic dissection.

Endovascular stent grafts **are considered experimental, investigational and/or unproven** for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms.

Policy Guidelines

None.

Description

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

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 of aortic aneurysm is dependent 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. (1) A total of 133 patients were identified; the primary clinical end points were cumulative rupture risk, rupture risk as a function of aneurysm size, and survival. The cumulative risk of rupture was 20% after 5 years. The 5-year risk of rupture as a function of aneurysm size at recognition was 0% for aneurysms less than 4 cm in diameter, 16% for those 4 to 5.9 cm, and 31% for aneurysms 6 cm or more. Interestingly, 79% of the ruptures occurred in women. Davies et al. (2002) reported on the yearly rupture or dissection rates in 721 patients with TAA. (2) 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. (3)

Surgical morbidity and mortality are typically subdivided into emergency and elective repair, with a focus on the incidence and risk of spinal cord ischemia, considered of the most devastating complications, resulting in paraparesis or paraplegia. The operative mortality of surgical repair of aneurysm of the descending and thoracoabdominal aorta is estimated at 6% to 12% and 10% to 15%, respectively, while mortality associated with emergent repair is considerably higher. (1, 4) In elective cases, predictors of operative mortality include renal insufficiency, increasing age, symptomatic aneurysm, the presence of dissection, and other comorbidities, such as 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. (5, 6) 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. (7-10) However, the optimal protective strategy is still uncertain. (11)

These significant morbidity and mortality 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 in patients with smaller symptomatic aneurysms.

Thoracic Aortic Dissection

Aortic dissection can be subdivided into type A, which involves the aortic arch, and type B, which is confined to the descending aorta. 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. Type B aortic dissections are classified by acuity (termed as complicated or uncomplicated) and chronicity and are summarized in Table 1.

Table 1. Aortic Dissection Acuity (12, 13)

Category	Description
Uncomplicated	• No rupture • No malperfusion • No high risk features
Complicated	• Rupture • Malperfusion
High risk	• Refractory pain • Refractory hyperfusion • Bloody pleural effusion

	• Aortic diameter >40 mm • Radiographic only malperfusion • Readmission • Entry tear: lesser curvature location • False lumen diameter >22 mm
Chronicity (time elapsed since the onset of symptoms)	• Hyperacute (<24 hours) • Acute (1 to 14 days) • Subacute (15 to 90 days) • Chronic (>90 days)

Mm: millimeter.

Treatment

Type A dissections are usually treated surgically, while type B dissections are often 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 recommend 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. Endovascular intervention has supplanted open repair or medical management alone as first-line treatment for complicated type B aortic dissection as a result of accumulated data indicating reduced morbidity and mortality. (14, 12)

Thoracic Aortic Rupture

Rupture of the thoracic aorta is a life-threatening emergency that is nearly always fatal if untreated. Thoracic artery rupture can result from a number of factors. Aneurysms can rupture due to progressive dilatation and pressure of the aortic wall. Rupture can also result from traumatic injury to the aorta, such as occurs with blunt chest trauma. Penetrating injuries that involve the aorta can also lead to rupture. Penetrating ulcers can occur in widespread atherosclerotic disease and lead to aortic rupture.

Treatment

Emergent repair of thoracic artery rupture is indicated in many cases in which there is free bleeding into the mediastinum and/or complete transection of the aortic wall. In some cases of aortic rupture, where the aortic media and adventitia are intact, watchful waiting with delayed surgical intervention is a treatment option. With the advent of thoracic endovascular aneurysm repair (TEVAR), the decision making for intervention may be altered, as there may be a greater tendency to intervene in borderline cases due to the potential for fewer adverse events with TEVAR.

Thoracic Endovascular Aneurysm Repair
TEVAR is an alternative to open surgery. TEVAR has been proposed for prophylactic treatment of aneurysms that meet criteria for surgical intervention, as well as for patients in need of emergency surgery for rupture or complications related to dissection. The standard open surgery technique for TAA is open operative repair with graft replacement of the diseased segment. This procedure requires 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.

Regulatory Status
A number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) for use in TAAs (see Table 2). FDA product code: MIH.

Table 2. Endovascular Grafts Approved for Use in Thoracic Aortic Aneurysms

Device	Manufacturer	Date Approved	PMA Number

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 aortic 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 is in the range of 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 Relay®Pro system is indicated for treatment of all lesions of the descending thoracic aortal, including Type B dissections and traumatic injuries.

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 indications for this graft and delivery system to include all lesions of the descending thoracic aorta, including type B dissections. (15) 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; and
- 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 to evaluate 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. (16) 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. (17) 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.

Rationale

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

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Aneurysms of the Descending Thoracic Aorta

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 individuals with type B (descending) thoracic aortic aneurysms (TAAs).

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

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. (18, 14)

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.

There are no RCTs assessing endovascular repair versus (vs) open surgery for thoracic aneurysms. The best evidence consists of nonrandomized comparative studies and systematic reviews of these studies. Representative prospective, nonrandomized studies, and selected systematic reviews are reviewed herein. 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). (19) No RCTs comparing endovascular repair with open surgical interventions were identified. Reports from nonrandomized studies suggested that endovascular repair is technically feasible and may reduce early negative outcomes, including death and paraplegia. However, endovascular repair is associated with late complications not often seen in open surgery, such as the development of leaks, graft migration, stent fractures, and aneurysm-related death. Patients receiving endovascular grafts also require more frequent surveillance with computed tomography scans with an increase in radiation exposure and will probably need surgical reintervention. Reviewers noted that high-quality RCTs are needed to evaluate longer term outcomes, but it is unlikely that such RCTs would be conducted with the current state 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. (20) Patients for both the graft group and the control group were selected using the same inclusion and exclusion criteria. After fractures in the wire frame of the TAG endoprosthesis were discovered in TAG 99-01, 51 patients underwent stent grafting with a modified TAG endoprosthesis at 11 sites in the subsequent TAG 03-03 study. The primary outcomes assessed in both TAG 99-01 and TAG 03-03 were the number of patients who had 1 or more major adverse events and the number of patients who did not experience device-related events 12 months after device deployment. The number of patients in the TAG 99-01 device group who experienced 1 or more major adverse event (42%) was significantly lower than the surgical repair control group (77%) at 1-year follow-up ($p<0.001$). Major adverse events included major bleeding as well as neurologic, pulmonary, renal function, and vascular complications. In the TAG 99-01 device group, 4 (3%) of 140 patients experienced paraplegia or paraparesis vs. 13 (14%) of 94 patients in the control group. The Makaroun report (2005) of the

TAG 99-01 study noted favorable aneurysm-related (97%) and overall survival (75%) rates and concluded that the Gore TAG device was a safe alternative treatment for descending TAAs.

Makaroun et al. (2008) reported on 5-year outcomes of the TAG 99-01 trial. (21) In this follow-up of 140 endograft patients and 96 non-contemporaneous controls, the authors concluded that endovascular treatment was superior to surgical repair at 5 years in anatomically suitable patients. At 5 years, the aneurysm-related mortality rate was lower for TAG patients (2.8%) than for open controls (11.7%; p=0.008). No differences in all-cause mortality rates were noted, with 68% of TAG patients and 67% of open controls surviving to 5 years. Endoleaks in the TAG group decreased from 8.1% at 1 month to 4.3% at 5 years. Five (3.6%) TAG patients had had major aneurysm-related reinterventions at 5 years. Compared with the 1-month baseline, sac size at 60 months decreased by 50% and increased in 19% of TAG patients. At 5 years, no ruptures, 1 migration, no collapse, and 20 instances of fracture in 19 patients were reported, all before the revision of the TAG graft. Trialists also suggested that, although sac enlargement was concerning, the modified device might help resolve this issue.

VALOR and VALOR II Trials

The Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) trial was a nonrandomized study conducted at 38 U.S. sites to assess the Talent stent graft. (22) The VALOR trial enrolled candidates for open surgical repair and compared 195 TAA patients (age, 70.2 years; male, 59%) with 189 retrospective open surgical repair controls (age, 69.6 years; male, 52.4%). Thirty-day (Talent group, 4/195 vs. surgery group, 15/189; p<0.1) and 12-month (Talent group, 31/192 vs. surgery group, 39/189; p<0.01) mortality were lower in the endovascular graft group than in the open surgery group.

The Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft in the Treatment of Descending Thoracic of Degenerative Etiology in Subjects Who Are Candidates for Endovascular Repair (VALOR II) was a prospective nonrandomized trial at 24 sites designed to evaluate the Valiant thoracic stent graft. (23) The VALOR II enrolled 160 patients who underwent stent grafting with the Valiant device, using enrollment criteria similar to VALOR. VALOR II outcomes were compared with those from the VALOR study. All-cause mortality at 12 months associated with the Valiant stent graft (12.6%) was statistically noninferior to the Talent stent graft (16.1%) and exceeded the primary effectiveness goal of 12-month successful aneurysm treatment (defined as absence of aneurysm growth >5 mm and of secondary procedures for type I/III endoleak).

Matsumoto et al. (2014) reported on rates of secondary procedures over 3-year follow-up for patients enrolled in the VALOR and VALOR II trials. (24) 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<0.001). The overall 3-year difference between groups in secondary procedure rates was driven by differences in early (<1 year) reintervention rates. This comparison suggested that the newer generation stent graft device may be associated with fewer reinterventions; however, the nonrandomized comparison and potential differences between patients in VALOR and VALOR II makes it difficult to draw firm conclusions about the relative efficacy of different devices.

Matsumara et al.

The Zenith TX2 device received premarketing approval from the U.S. Food and Drug Administration based on results of the trial reported by Matsumara et al. (2008). (25) This prospective cohort trial compared 160 TEVAR patients (age, 72 years; male, 72%) with 70 open surgery patients (age, 68 years; male, 60%). The trial arms were comparable in the previous history of cardiovascular and other vascular disease. The TEVAR patients had a lower American Society of Anesthesiologist classification (p<0.01) and higher Society of Vascular Surgery/International. Society of Cardiovascular Surgery risk score (p=0.03). The 30-day survival rate for the endovascular group (98.1%) was noninferior to the control group (94.3%; p<0.01). The 30-day severe morbidity composite index (cumulative mean number of events per patient) was significantly lower in the endovascular group (0.2) than in the control group (0.7; p<0.01). At 12 months, aneurysm growth was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103), and stent migration in 2.8% (3/107). At 12 months, aneurysm enlargement was identified in 7.1% of the endovascular patients, endoleak occurred in 3.9% (4/103) of patients, and migration in 2.8% (3/107) of patients.

Matsumara et al. (2014) published 5-year follow-up from the Zenith TX2 cohort trial. (26) The 70 patients in the open surgical control group underwent clinical evaluation before discharge or at 1 month and then at 12 months and yearly after that, up to 5 years. TEVAR patients had follow-up at 1-, 6-, and 12-months post-procedure and yearly after that. Of the 160 TEVAR patients, 2 did not have successful device deployment and only had a follow-up to 30 days; an additional 32 were lost to follow-up. Five-year survival was 62.9% for the TEVAR group and 62.8% for the open surgical group (p=0.88). Kaplan-Meier estimates for freedom from severe morbidity was significantly higher in the TEVAR group than in the open surgical control group (87.3% vs. 64.3% at 1 year; 79.1% vs. 61.2% at 5 years; all p<0.001). Secondary interventions occurred at similar rates between the endovascular and open surgical control patient groups during follow-up through 5 years. While this trial is limited by some loss to follow-up, it did suggest that the early morbidity benefit associated with TEVAR persists over time and that rates of secondary interventions may be comparable with the open surgical repair.

<u>Section Summary: Aneurysms of the Descending Thoracic Aorta</u>

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 individuals with uncomplicated type B (descending) thoracic aortic dissections.

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

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.

Acute Or Subacute Uncomplicated Type B Aortic Dissections

Sá et al. (2024) published a meta-analysis of midterm outcomes of endovascular vs. medical therapy for uncomplicated Type B aortic dissection. (27) The review included both acute and chronic dissection and the results from the RCTs in the review are already discussed in the following sections. The meta-analyses included 10 studies (8 observational; 2 RCTs) with 17,906 participants (2,332 in the TEVAR groups vs 15,574 in the medical therapy groups). The median follow-up time was 4.3 years (intra quartile range, 1.7 to 5.5 years). Participants who underwent TEVAR had a statistically significantly lower risk of all cause death (HR=0.79; 95% CI, 0.72 to 0.87; p<.01) and aortic related death (HR=0.43; 95% CI, 0.30 to 0.62; p <.01). However, the GRADE certainty was rated as 'low' for both outcomes due primarily to the serious risk of confounding in the observational studies.

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). (28) 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). (29) A summary of key trial characteristics is presented in Table 3. 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 4. 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 post-procedure; during follow-up, 1 death (cardiac arrest) occurred in the TEVAR group. Study relevance, conduct, and design limitations are summarized in Tables 5 and 6.

Table 3. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
Brunkwall et al. (2014) (29)	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 4. 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
Brukwall et al. (2014) (29)					
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 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Brunkwall et al. (2014) (29)	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.

[a] 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.

[b] 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.

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

[d] 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.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Brunkwall et al. (2014) (29)				7. Challenges in obtaining quality follow-up imaging resulting in 14 failures due to imaging issues/ dropouts.	4. Not powered for mortality outcomes	

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

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

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] 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.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] 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

Ianuzzi and colleagues published a large analysis of adults with acute uncomplicated type B aortic dissection from the California Office of Statewide Hospital Planning Development database in 2018. (30) Patients admitted between 2000 and 2010 with an ICD-9 code for thoracic aortic dissection or thoracoabdominal aortic dissection were included, with grouping according to ICD-9 codes for TEVAR, open repair, or neither (medical management); patients whose admission was non-emergent or with traumatic or complicated dissections were excluded. The analysis included 9165 patients; 95% (n=8717) were managed medically, while 2.9% (n=266) and 2.0% (n=182) underwent TEVAR and open repair, respectively. Patients in the TEVAR group were more likely to be male and of non-White race compared to other groups (p<.01 for each). Rates of major complications were higher in patients who underwent open repair (72%) compared to TEVAR and medical management (55% and 49%, respectively; p<0.01). Similarly, inpatient mortality was higher in patients who underwent open repair (14%) compared to those who underwent TEVAR or medical management (7.1% and 6.3%, respectively; p<0.01). With median follow-up of 2.3 years for open repair and medical therapy and 1.5 years for TEVAR, OS was significantly prolonged in patients who underwent TEVAR (p<0.01). Multivariable Cox proportional hazards regression indicated TEVAR remained associated with prolonged survival compared to medical management (HR, 0.68; 95% CI, 0.55 to 0.83) but not to open repair (HR, 1.0; 95% CI, 0.82 to 1.3) after adjustment for history of congestive heart failure, cocaine use, high Charlson Comorbidity index, age, and renal failure.

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). (31) 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=0.622), but significantly increased rates of adverse events with TEVAR (17 patients [11.7%] vs. 4 patients [2.8%]; p=0.003). 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=0.028); similar trends favoring TEVAR were also seen for freedom from aortic-related death (overall p=0.044). 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=0.024). Endoleaks with TEVAR occurred in 2.1%, 3.6%, and 6% of patients who received TEVAR at 1, 3, and 5 years, respectively.

Chronic Uncomplicated Type B Aorta Dissections

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. (32) A total of 39 studies were included; 2 of these (N=195 patients) 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 radio [OR], 4.13; 95% CI, 1.10 to 15.4; p = 0.035). Adverse neurologic events were significantly higher with open surgery. Survival analysis did not indicate a benefit of one technique over the other at 1 year (OR, 0.73; 95% CI, 0.34 to 1.55, p = 0.41) or 3 years (OR, 1.19; 95% CI, 0.42 to 3.32, p = 0.73). Compared with open surgery, endovascular repair significantly increased reintervention risk (OR, 0.34; 95% CI, 0.16 to 0.69; p = 0.003). 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 two 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. (33) 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

The INSTEAD trial compared TEVAR with best medical therapy for patients who had subacute or chronic uncomplicated thoracic aorta dissections. The INSTEAD trial was reported by Neinaber et al. (2010). (34) 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. Median time between onset of dissection and randomization was 45 days and 39 days in the TEVAR and medical management groups, respectively, indicating most patients had subacute aortic dissections. The primary end point (all-cause mortality at 1 year) did not differ significantly between groups: the cumulative survival rate was 91.3% in the endovascular group and 97.0% in the medical management group (p=0.16). In addition, the aorta-related mortality rate did not differ (5.7% vs. 3.0%, respectively; p=0.42). There were 2 cases of ischemic spinal cord injury, one in each group. Seven (10.6%) patients in the medical group crossed over to the stent graft group, and one from each group required open surgical intervention within the 12-month study period. An additional stent graft for false lumen expansion was required in six patients. A secondary measure of aortic remodeling was reported more frequently in the endovascular repair group (91.3% vs. 19.4%, respectively; p<0.001), but the clinical significance of this finding is unknown. Three adverse neurologic events occurred in the endovascular group compared with in the medical-only arm. Trialists concluded that elective stent graft placement did not improve survival at 1 year.

Nienaber et al. (2013) published long-term follow-up results from the INSTEAD trial (INSTEAD-XL). (35) Patients were followed for a minimum 5 years (maximum, 8 years); the median interval until death or latest follow-up was 69 months (interquartile range, 62-83 months); there was no loss to follow-up. The risk of all-cause mortality did not differ significantly between groups at 5 years post-randomization (11.1% in the endovascular repair group vs. 19.3% in the medical therapy group, p=0.13). Five-year aorta-specific mortality was significantly lower in patients who underwent TEVAR compared to those who received medical therapy alone (6.9% vs 19.3%; p=0.045). For the combined end point of disease progression (aorta-specific death, crossover/conversion, secondary procedures) and aorta-specific events at 5 years of follow-up, freedom from the combined end point was 53.9% with medical therapy alone and 73.0% with TEVAR; however, among patients who had not experienced a disease progression event at 2 years, 5-year rates of freedom from progression favored TEVAR (HR, 0.112; 95% CI, 0.03 to 0.49; p=0.004).

Retrospective Studies
Several retrospective studies have compared TEVAR with open surgical repair in patients with chronic type B aortic dissection. Leshnower et al. (2013) analyzed a single-center registry cohort of patients with chronic type B aortic dissections who underwent elective TEVAR (n=31) or open repair (n=58) between 2005 and 2012. (36) Mean follow-up was 21 months (range, 1 to 61 months). The cohort that underwent TEVAR tended to be older (mean age 67 years vs 57 years, p<0.001) than those who underwent open repair. No early (30-day) mortality occurred in the TEVAR group, compared with 10.3% in the open repair group (p=0.08); no cases of stroke, paraplegia, dialysis-dependent renal failure, or tracheostomy occurred in the TEVAR group, compared to 3.4% (p=0.53), 12.1% (p=0.04), 10.3% (p=0.08), and 13.8% (p=0.04) in the open repair group, respectively. Hospital and ICU length of stay were significantly longer in the open repair group than the TEVAR group (mean 21 days vs 7 days and 13 days vs 2 days, respectively; p<0.001 for both). Freedom from combined aorta-related death, rupture, or reintervention in the TEVAR and open repair groups was 96.6% and 89.1% at 1 year and 76.9% and 82.5% at both 3 and 5 years (p=0.90), respectively.

Andersen et al. (2014) performed a similar single-center retrospective analysis in patients with chronic type B aortic dissection who underwent TEVAR (n=44), other endovascular approaches (n=31), or open repair (n= 32) between 2005 and 2013. (37) There were no cases of in-hospital (30-day) stroke, paraplegia, or death in patients who underwent TEVAR, whereas these events occurred in 16%, 9%, and 6% of patients who underwent open repair, respectively. Post-operative length of stay was longer in patients who underwent open repair than those who underwent endovascular repair (median 8 days vs 4 days; p=0.001). With median follow-up of 34 months, cumulative OS was similar at 1 (86% and 88%) and 5 years (65% and 79%) for endovascular and open repair. Significantly more patients who underwent endovascular repair required subsequent reintervention than those who underwent open repair (24% vs 0, respectively; p=0.001).

van Bogerijen et al. (2015) performed a single-center retrospective analysis in patients with chronic type B aortic dissection who underwent TEVAR (n=32) or open repair (n=90) between 1993 and 2013. (38) Patients who underwent TEVAR tended to be older (mean 69.2 vs 56.4 years; p<0.001) and were more likely to be female (53.1% vs 22.2%; p=0.001) and have chronic obstructive pulmonary disease (25% vs 2.2%; p<0.001). Rates of early (30-day) mortality (0 vs 5.6%; p=0.173), cerebrovascular accident (3.1% vs 1.1%; p=0.457), permanent spinal cord ischemia (0 vs 4.4%; p=0.572), need for dialysis (3.1% vs 7.8%; p=0.361), and tracheostomy (0 vs 4.4%; p=0.225) were similar between the TEVAR and open repair groups. Hospital length of stay was significantly longer with open repair than TEVAR (median 13.6 days vs 6.5 days; p<0.001). With median follow-up of 34.8 months, OS at 5 years was similar between TEVAR and open repair (78.1% vs 86.7%; p=0.232), whereas 3-year freedom from aortic rupture or reintervention was lower with TEVAR than open repair (87.5% vs 96.7%; p=0.026).

Section Summary: Chronic Uncomplicated Type B Aortic Dissections

For patients with chronic uncomplicated type B dissections of the thoracic aorta, an RCT reported that short-term (1 year) and long-term (5 year) all-cause mortality outcomes did not differ significantly between TEVAR and medical management in stable patients with type B aortic dissection. Another 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. In a systematic review of mostly non comparative 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 Aorta 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 individuals with complicated type B (descending) thoracic aortic dissections.

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

Populations

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

Interventions

The therapy being considered is endovascular repair. Thoracic endovascular aortic repair is the current standard of care for repairs of complicated type B (descending) aortic dissections in patients with suitable anatomy, as there is a significant morbidity and mortality benefit when compared to open surgical repair or medical management. (14, 12)

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.

<u>Study Selection Criteria</u>
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.

There are no RCTs assessing endovascular repair versus open surgery for complicated type B (descending) aortic dissections. 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. Since TEVAR is the current standard of care for repair of complicated type B (descending) aortic dissection 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
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). (39) "Complicated" dissection was defined as aortic rupture and/or the presence of organ malperfusion syndromes. The rate of 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 [61%]), stroke (n=70 [59%]), and endoleak (n=110 [50%]).

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. (40) “Complicated dissections” were defined as those with aortic rupture, visceral and renal ischemia, lower-extremity ischemia, or spinal cord ischemia, or with expansion to the aortic arch or proximal descending aorta with a total diameter of 4.5 cm or more. Reviewers included

30 studies on TEVAR, 15 studies on best medical therapy, and 9 studies on surgical repair. For the 2531 patients with acute, complicated type B aortic dissection treated with TEVAR, the pooled 30-day/in-hospital mortality rate was 7.3% (95% CI, 5.3% to 9.6%). Survival rates ranged from 62% to 100% at 1 year and from 61% to 87% at 5 years. For the 1276 patients with acute complicated type B aortic dissection treated with open repair, the pooled 30-day/in-hospital mortality rate was 19.0% (95% CI, 16.8% to 21.1%). Survival rates ranged from 74.1% to 86.0% at 1 year and from 44.0% to 82.6% at 5 years. Direct comparisons between treatment groups were not reported, and the trial did not account for between-group differences (other than treatment modality), which limits conclusions that may be drawn.

Randomized Controlled Trials
There are no RCTs for treatment of acute, complicated type B dissections.

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%]), 315 [37.2%] of whom had complicated dissections) or TEVAR (n=276 [24.4%], 163 [61.7%] of whom had complicated dissections) therapy. (41) At baseline, prior to propensity scoring and matching, TEVAR patients were more likely than medical therapy patients to present with pulse deficit (28.3% vs. 13.4%; p<0.001), lower extremity ischemia (16.8% vs. 3.6%; p<0.001), 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<0.001) or "severe or worst ever" (97.4% vs. 92.3%; p=0.010). 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=0.018); 1-year mortality rates were similar between groups (8.1% vs. 9.8%, respectively; p=0.604). Although the study was observational with the potential for selection bias, the participants in the TEVAR group were at higher risk and the expected direction of the bias would be to favor medical therapy.

Section Summary: Acute, Complicated Type B Aorta Dissections
There are no RCTs comparing TEVAR with open surgery for repair of complicated type B (descending) aortic dissections, with the best evidence on this question consisting of nonrandomized, comparative studies. Systematic reviews with meta-analysis of available data indicate that while TEVAR carries risk of complications that overlap incompletely with those of open surgery, there is consistently lower risk of early mortality with TEVAR relative to open surgery, and similar or superior long-term survival with TEVAR relative to open surgery or medical management alone.

Traumatic 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 individuals with traumatic descending aortic tears or rupture.

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

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

Interventions
The therapy being considered is endovascular repair. Thoracic endovascular aortic repair is the current standard of care for repairs of traumatic descending aortic tears or rupture in patients with suitable anatomy, as there is a significant morbidity and mortality benefit when compared to open surgical repair. (14)

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.

<u>Study Selection Criteria</u>
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.

There are no RCTs assessing endovascular repair versus open surgery for traumatic descending aortic tears or rupture. 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. Since TEVAR is the current standard of care for traumatic descending aortic tears or rupture, for this section, the addition of newer publications that address important safety concerns and/or patient selection criteria is prioritized.

<u>Systematic Reviews</u>

Gennai et al. (2023) performed a systematic review with meta-analysis of studies reporting long-term outcomes (mean follow-up >5 years) in patients who underwent TEVAR for blunt traumatic aortic injury. (42) The authors included 11 studies with a total of 389 patients over 8.2 years of estimated follow-up. The pooled survival estimate was 95.6% (95% CI, 88.1% to 99.8%) Reintervention more than 30 days after TEVAR occurred in 2.1% of patients; bird-beak (poor apposition of the graft fabric to the inner curve of the aortic arch) was reported in 38.7% (data contributed by 3 studies), left arm claudication was reported in 3.1%, in-stent thrombosis was reported in 1.9% (data contributed by 5 studies), and endoleaks were reported in 0.5%.

Harky et al. (2020) performed a systematic review with meta-analysis of observational studies comparing outcomes in patients who underwent TEVAR or open repair for traumatic ruptured thoracic aorta. (43) The analysis included 1968 patients from 21 studies. In pooled analysis, TEVAR was associated with lower rates of 30-day mortality than open repair (OR, 2.94; 95% CI, 1.92 to 4.49); similar mortality rates between TEVAR and open surgery were noted in analyses at 1 year (8.7% vs 17%; p=0.05) and 5 years (17% vs 24%; p=0.33), but data for these outcomes were only available from 6 and 2 studies, respectively. No difference was identified in rates of reintervention; most reintervention for patients who underwent TEVAR was related to endoleaks, whereas most reintervention in patients who underwent open repair was related to bleeding. The authors also did not identify differences in rates of neurologic complications, vascular complications, renal failure, or other safety-related outcomes.

Lee et al. (2011) summarized data on the use of TEVAR for traumatic thoracic aortic injuries to aid development of practice guidelines. (44) 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<0.01). The evidence was of very low quality, and there was a lack of follow-up data.

<u>Randomized Controlled Trials</u>
There are no RCTs for the treatment of traumatic tears or rupture of the descending aorta.

<u>Nonrandomized Comparative Studies</u>
Scalea et al. (2019) retrospectively analyzed registry data from 3774 patients with blunt thoracic aortic injury who underwent TEVAR, open repair, or medical management between 2003 and 2013. (45) Most cases (70%) were managed non-operatively. After the first FDA approval of TEVAR devices, significant increases in TEVAR and decreases in open repair were noted over time. Significant reductions in median intensive care unit length of stay and mortality were noted over the study period in the overall cohort; in a propensity score-matched analysis, TEVAR was associated with lower mortality than open repair (8.1% vs. 16.2%; p=0.05).

Additional nonrandomized comparative studies using trauma registry data have found lower short-term mortality, complications, and hospital or ICU length of stay with endovascular repair compared to open surgery. (45-47)

Section Summary: Traumatic Tears and Rupture of the Descending Aorta

There are no RCTs comparing TEVAR with open surgery for patients with traumatic tears or rupture of the descending aorta, with the best evidence on this question consisting of nonrandomized, comparative studies. Systematic reviews with meta-analysis of available data indicate that in patients in whom intervention is indicated, there is consistently lower risk of early mortality with TEVAR relative to open surgery, and similar or superior long-term survival with TEVAR relative to open surgery. Long-term follow-up of patients who underwent TEVAR in this setting indicate low overall rates of complications; although a relatively high rate of bird-beak has been reported, this did not appear to translate to high rates of reintervention.

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 individuals with ascending aortic disorders.

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

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 traumatic 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.

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. (48) 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). (49) 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). (50) Appoo et al. (2015) reported on imaging-related outcomes for 16 patients who underwent TEVAR for aortic arch or ascending aorta. (51)

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

Summary of Evidence
For individuals who have type B (descending) thoracic aortic aneurysms (TAAs) who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. The available nonrandomized comparative studies have consistently reported reduced short-term mortality and morbidity compared with surgical repair. Although these types of studies are subject to selection bias and other methodologic limitations, the consistency of the findings of equivalent or reduced short-term mortality and fewer early complications across populations with different characteristics supports the conclusion that thoracic endovascular aneurysm repair (TEVAR) is a safer procedure in the short term. The 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 randomized controlled trials (RCTs), systematic reviews, and retrospective cohort studies. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. In the INSTEAD trial there were no statistically significant differences between the endovascular and medical groups for OS at 1 year or at 5 years. At 5 years of follow-up, aorta-specific mortality (7% versus 19%) was significantly lower for endovascular versus medical treatment. In the ADSORB trial, there were significantly fewer events of the composite outcome of incomplete/no false lumen thrombosis, aortic dilation, or aortic rupture in the endovascular group in the per protocol analysis, but the trial had several limitations and was not designed for mortality outcomes. An ongoing RCT (NCT02622542) is designed to compare 5-year all-cause mortality for best medical therapy alone versus best medical therapy with thoracic endovascular aortic repair for uncomplicated acute type B aortic dissection. 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. Systematic reviews of the available nonrandomized comparative studies consistently indicate benefits in early morbidity and mortality with TEVAR relative to open repair, as well as similar or superior long-term survival outcomes compared to open repair or medical management alone. Although these studies carry inherent limitations and the interventions carry complication risks that do not completely overlap, the accrued evidence favors use of TEVAR over open repair in suitable patients. The evidence is sufficient 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 overall survival, morbid events, and treatment-related mortality and morbidity. Systematic reviews of the available nonrandomized comparative studies consistently indicate benefit in early mortality and similar or superior long-term survival outcomes with TEVAR relative to open repair, with low rates of complications requiring reintervention with long-term follow-up. The evidence is sufficient to determine that the technology results in an improvement in the net health outcomes.

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

Practice Guidelines and Position Statements

American College of Cardiology/American Heart Association

In 2022, the American College of Cardiology and American Heart Association published guidelines for the diagnosis and management of aortic disease. (14) The guideline included the recommendations regarding thoracic aortic disorders below (Table 7).

Table 7. American College of Cardiology/American Heart Association 2022 Guideline on Aortic Disease

Recommendations	COR	LOE
In patients without Marfan syndrome, Loeys-Dietz syndrome, or vascular Ehlers-Danlos syndrome, who have a descending TAA that meets criteria for intervention and anatomy suitable for endovascular repair, TEVAR is recommended over open surgery.	1	B-NR
In patients with ruptured descending TAA who are anatomic candidates for endovascular repair, TEVAR is recommended over open repair because of decreased perioperative death and morbidity.	1	B-NR
In patients with ruptured TAAA requiring intervention, open repair is recommended.	1	B-NR

In patients with ruptured TAAA requiring intervention, provided that the patient is hemodynamically stable, endovascular repair may be reasonable in centers with endovascular expertise and access to appropriate endovascular stent grafts.	2b	C-LD
In patients with Marfan syndrome, Loeys-Dietz syndrome, or vascular Ehlers-Danlos syndrome and intact TAAA requiring intervention, open repair is recommended over endovascular repair.	1	C-LD
In patients with intact degenerative TAAA and suitable anatomy, endovascular repair with fenestrated stent grafts, branched stent grafts, or both may be considered in centers with endovascular expertise and access to appropriate endovascular stent grafts.	2b	B-NR
In patients with rupture [of acute type B aortic dissection], in the presence of suitable anatomy, endovascular stent grafting, rather than open surgical repair, is recommended.	1	C-EO
In patients with other complications [of acute type B aortic dissection, besides rupture], in the presence of suitable anatomy, the use of endovascular approaches, rather than open surgical repair, is reasonable.	2a	C-LD
In patients with uncomplicated acute type B aortic dissection who have high-risk anatomic features, endovascular management may be considered[a].	2b	B-R
In patients with blunt traumatic thoracic aortic injury who meet indications for repair and with appropriate anatomy, TEVAR is recommended over open repair.	1	B-NR

COR: class of recommendation; EO: expert opinion; LD: limited data; LOE: level of evidence; NR: non-randomized; R: randomized; TAA: thoracic aortic aneurysm; TAA: thoracoabdominal aortic aneurysm; TEVAR: thoracic endovascular aortic repair.

[a] High-risk anatomic features include 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.

Society of Thoracic Surgeons/American Association for Thoracic Surgery

The Society of Thoracic Surgeons and American Association for Thoracic Surgery published a guideline on the management of type B aortic dissection in 2022. (12) The guideline included the recommendations regarding thoracic aortic disorders below (Table 8).

Table 8. Society of Thoracic Surgeons/American Association for Thoracic Surgery 2022 Guideline on Type B Aortic Dissection

Recommendation	COR	LOE
TEVAR is indicated for complicated hyperacute, acute, or subacute TBADs with rupture and/or malperfusion and favorable anatomy for TEVAR.	1	B-NR
Open surgical repair for complicated hyperacute, acute, or subacute TBADs should be considered for those patients with unsuitable anatomy for TEVAR.	2a	B-NR

OMT is the recommended treatment for patients with uncomplicated TBAD.	1	B-NR
Prophylactic TEVAR may be considered in patients with uncomplicated TBAD to reduce late aortic-related adverse events and aortic-related death.	2b	B-NR
Open surgical repair should be considered for patients with chronic TBAD with indications for intervention, unless comorbidities are prohibitive, or anatomy is not suitable for TEVAR.	2a	B-NR
TEVAR is reasonable for patients with chronic TBAD with an indication for intervention with suitable anatomy (adequate landing zone, absence of ascending or arch aneurysm) but who are at high risk for complications of open repair due to comorbidities.	2a	B-NR
TEVAR alone as sole therapy is not recommended in patients with chronic TBAD who have a large abdominal aortic aneurysm, an inadequate distal landing zone, and/or large distal reentry tears.	3	C-LD

COR: class of recommendation; LD: limited data; LOE: level of evidence; NR: non-randomized; OMT: optimal medical therapy; TBAD: type B aortic dissection; TEVAR: thoracic endovascular aortic repair.

Society for Vascular Surgery

In 2021, the Society for Vascular Surgery published guidelines on TEVAR for descending TAAs. (18) The guideline included the following recommendations (Table 9).

Table 9. 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
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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 10.

Table 10. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04808661	EndovaScular Versus mediCaL mAnagement of Uncomplicated Type B Intramural heMatoma Trial (ESCLAIM)	154	Mar 2024
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
NCT06087029	IMPRoving Outcomes in Vascular DisEase-Aortic Dissection (IMPROVE-AD)	1100	Jun 2030
NCT05215587	Scandinavian Trial of Uncomplicated Aortic Dissection Therapy (SUNDAY)	554	Dec 2030

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	33880, 33881, 33883, 33884, 33886, 33889, 75956, 75957, 75958, 75959
HCPCS Codes	None

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	**Description of Change**
12/15/2024	Document updated with literature review. Coverage unchanged. References 12-14, 27, 30, 36-38, 42-43 added; others updated; some removed.
12/01/2023	Reviewed. No changes.
10/01/2022	Document updated with literature review. Coverage unchanged. References 14-16, 25, 27, 32, 41 and 46 added; others removed.
01/01/2022	Reviewed. No changes.
09/15/2020	Document updated with literature review. Coverage unchanged. References 24, 32-34 added.

08/01/2019	Reviewed. No changes.
02/15/2019	Document updated with literature review. Coverage statements edited for clarity; intent of statements unchanged. Added References 14, 29-31; numerous references removed. Title changed from "Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections".
09/01/2017	Reviewed. No changes.
12/15/2016	Document updated with literature review. The following coverage was added: Rupture of the descending thoracic aorta was added to the following statement: Endovascular stent grafts, using devices approved by the U.S. Food and Drug Administration (FDA) for their approved specifications, may be considered medically necessary for the treatment of: 3. Rupture of the descending thoracic aorta.
02/01/2015	Document updated with literature review. The following phrase: for the treatment of thoracic aortic lesions that do not meet the above criteria, including but not limited to; was added to the following coverage statement: Endovascular stent grafts are considered experimental., investigational. and/or unproven for the treatment of thoracic aortic lesions that do not meet the above criteria, including but not limited to thoracic aortic arch aneurysms.
12/01/2012	Document updated with literature review. The following was changed: Endovascular stent grafts, using devices approved by the U.S. Food and Drug Administration (FDA) for their approved specifications, may be considered medically necessary for the treatment of acute, complicated (organ or limb ischemia or rupture) Type B (i.e., descending aorta) thoracic aortic dissection
09/15/2010	Updated document with literature review. Coverage unchanged.
10/01/2008	Revised/updated entire document
03/15/2006	Revised/updated entire document
05/01/2005	New medical document