Endovascular Stent Grafts for Disorders of the Thoracic Aorta

Policy # 00181
Original Effective Date: 09/22/2005
Current Effective Date: 08/14/2023

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

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

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

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

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

Patient Selection Criteria
Coverage eligibility may be considered for endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) when ANY of the following criteria are met:

- Descending thoracic aortic aneurysms (TAAs) used according to FDA-approved specifications (see Policy Guidelines section); OR
- Acute, complicated (organ or limb ischemia or rupture) type B descending thoracic aortic dissection when distal to the aortic arch; OR
- Traumatic descending aortic tears or rupture.
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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of endovascular stent grafts for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated or type A aortic dissection to be investigational.*

Based on review of available data, the Company considers the use of endovascular stent grafts for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms to be investigational.*

Policy Guidelines
Endograft placement relies on nonaneurysmal aortic segments proximal and distal to the aneurysm and/or dissection for anchoring, and a maximal graft diameter that varies by device. For example, the Gore TAG\textsuperscript{®} endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for “≥2 cm non-aneurysmal aorta proximal and distal to the aneurysm” and an "aortic inner diameter of 23-37 mm." The Zenith TX2\textsuperscript{®} device is approved by FDA for nonaneurysmal aortic segments "of at least 25 mm in length" and a "diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm."

Background/Overview
Thoracic Aortic Aneurysms
Aortic aneurysms are arterial dilations associated with age, atherosclerosis, and hypertension, as well as some congenital connective tissue disorders. The likelihood of significant sequelae from aortic aneurysm depends on the location, size, and underlying disease state. Left untreated, these aneurysms tend to enlarge over time, increasing the risk of rupture or dissection. Of greatest concern is the tendency for aortic aneurysms to rupture, with severe consequences including death. Another significant adverse occurrence of aortic aneurysm is aortic dissection, in which an intimal tear permits blood to enter the potential space between the intima and the muscular wall of the aorta. Stable dissections may be managed medically; however, dissections that impinge on the true lumen of the aorta or occlude branching vessels are a surgical emergency.
Treatment

Indications for the elective surgical repair of aortic aneurysms are based on estimates of the prognosis of the untreated aneurysm balanced against the morbidity and mortality of the intervention. The prognosis of thoracic aortic aneurysm (TAA) is typically reported regarding the risk of rupture according to size and location (ie, the ascending or descending or thoracoabdominal aorta). While several studies have estimated the risk of rupture of untreated aneurysms, these studies have excluded patients who underwent surgical repair; therefore, the true natural history of thoracic aneurysms is unknown. Clouse et al (1998) performed a population-based study of TAA diagnosed in Minnesota, between 1980 and 1994. A total of 133 patients were identified; the primary clinical 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. A total of 304 patients were dissection-free at presentation; their natural history was followed for rupture, dissection, and death. Patients were excluded from analysis once the operation occurred. Not surprisingly, the authors reported that aneurysm size had a profound impact on outcomes. For example, based on their modeling, a patient with an aneurysm exceeding 6 cm in diameter could expect a yearly rate of rupture or dissection of at least 6.9% and a death rate of 11.8%. In a previous report, these same authors suggested surgical intervention of a descending aorta aneurysm if its diameter measured 6.5 cm.

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

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

Thoracic Aortic Dissection
Aortic dissection can be subdivided into type A, which involves the aortic arch, and type B, which is confined to the descending aorta. Dissections associated with obstruction and ischemia can also be subdivided into an obstruction caused by an intimal tear at branch vessel orifices, or by compression of the true lumen by the pressurized false lumen.

Treatment
Type A dissections are usually treated surgically, while type B dissections are usually treated medically, with surgery indicated for serious complications, such as visceral ischemia, impending rupture, intractable pain, or sudden reduction in aortic size. It has been proposed that endovascular therapy can repair the latter group of dissections by redirecting flow into the true lumen. The success of endovascular stent grafts of abdominal aortic aneurysms has created interest in applying the same technology to the aneurysms and dissections of the descending or thoracoabdominal aorta. As noted, type A dissections (involving the ascending aorta) are treated surgically. There is more controversy regarding the optimal treatment of type B dissections (ie, limited to the descending aorta). In general, chronic, stable type B dissections are managed medically, although some surgeons have recommended a more aggressive approach for younger patients in otherwise good health. When serious complications arise from a type B dissection (ie, shock or visceral ischemia), surgical intervention is usually indicated. Although there is an estimated 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. 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
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these complications are similar to those encountered with open repair (eg, paraplegia, cardiopulmonary events), and others are unique to TEVAR (eg, access site complications).

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

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

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

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

PMA: premarket approval.

The Gore TAG®‡ Thoracic Endoprosthesis is indicated for endovascular repair of aneurysms of the descending thoracic aorta. Use of this device requires patients to have adequate iliac/femoral access, aortic inner diameter in the range of 23 to 37 mm, and 2 cm or more nonaneurysmal aorta proximal and distal to the aneurysm. In 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.

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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. 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. 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. 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.
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FDA product code: MIH.

Rationale/Source
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

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 overall survival (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 randomized controlled trials (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
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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
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.
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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. The guidelines offered the following recommendations (Table 2).

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

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

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.
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National Institute for Health and Care Excellence
In 2005, NICE published guidelines on endovascular stent-graft placement in thoracic aortic aneurysms (TAAs) and dissections. 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. The guideline included the following recommendations (Table 3).

Table 3. Society for Vascular Surgery Guidelines on Thoracic Endovascular Aortic Repair for Descending Aortic Aneurysms

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>LOR</th>
<th>QOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>1</td>
<td>A</td>
</tr>
<tr>
<td>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</td>
<td>1</td>
<td>B</td>
</tr>
<tr>
<td>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</td>
<td>2</td>
<td>C</td>
</tr>
<tr>
<td>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</td>
<td>1</td>
<td>B</td>
</tr>
<tr>
<td>We suggest TEVAR in selected cases of asymptomatic penetrating aortic ulcer in patients who have at-risk characteristics for growth or rupture</td>
<td>2</td>
<td>B</td>
</tr>
</tbody>
</table>
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We suggest TEVAR for symptomatic mycotic/infected TAA as a temporizing measure, but data demonstrating long-term benefit are lacking

We recommend TEVAR over open repair for the treatment of ruptured DTA when anatomically feasible

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

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 4.

Table 4. Summary of Key Trials

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

NCT: national clinical trial.

References


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Endovascular Stent Grafts for Disorders of the Thoracic Aorta

Policy # 00181
Original Effective Date: 09/22/2005
Current Effective Date: 08/14/2023


Policy History
Original Effective Date: 09/22/2005
Current Effective Date: 08/14/2023
09/07/2005 Medical Director review
09/20/2005 Medical Policy Committee review
09/22/2005 Quality Care Advisory Council approval
05/03/2006 Medical Director review
05/17/2006 Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/07/2007 Medical Director review
11/05/2008 Medical Director review

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11/18/2008  Medical Policy Committee approval. Coverage eligibility unchanged.
11/12/2009  Medical Policy Committee approval
11/04/2010  Medical Policy Committee review
11/03/2011  Medical Policy Committee review
11/16/2011  Medical Policy Implementation Committee approval. Eligible for coverage statements reformatted to clarify the intent that use is for specific types of aneurysms without dissection, for complicated Type B dissections and for traumatic aortic injury (when specific conditions are met). Added a Note to the coverage section for clarification.
11/01/2012  Medical Policy Committee review
11/07/2013  Medical Policy Committee review
11/20/2013  Medical Policy Implementation Committee approval. Eligible for coverage indication added for acute rupture of the thoracic aorta.
11/06/2014  Medical Policy Committee review
11/21/2014  Medical Policy Implementation Committee approval. Title changed from “Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections” to “Endovascular Stent Grafts for Disorders of the Thoracic Aorta”. Coverage eligibility unchanged.
08/03/2015  Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015  Medical Policy Committee review
11/16/2015  Medical Policy Implementation Committee approval. Updated INV statement.
11/03/2016  Medical Policy Committee review
01/01/2017  Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017  Medical Policy Committee review

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01/01/2018  Coding update
11/08/2018  Medical Policy Committee review
11/21/2018  Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Moved the “Note” from the coverage section to a newly created Policy Guidelines section.
11/07/2019  Medical Policy Committee review
04/02/2020  Medical Policy Committee review
04/08/2020  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021  Medical Policy Committee review
04/14/2021  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022  Medical Policy Committee review
04/13/2022  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023  Medical Policy Committee review
04/12/2023  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023  Medical Policy Committee review
07/12/2023  Medical Policy Implementation Committee approval. Replaced the “When Services Are Eligible for Coverage” section with “When Services May Be Eligible for Coverage” since the policy has bulleted criteria.

Next Scheduled Review Date: 07/2024

**Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of*
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descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

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

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>33880, 33881, 33883, 33884, 33886, 75956, 75958, 75959</td>
</tr>
<tr>
<td></td>
<td>Add code effective 08/01/2023: 75957</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

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

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
   A. In accordance with nationally accepted standards of medical practice;
   B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
   C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.
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