Endovascular Stent Grafts for Disorders of the Thoracic Aorta

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

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

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

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

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

- Descending thoracic aortic aneurysms (TAAs) used according to FDA-approved specifications (see Policy Guidelines section);
- Acute, complicated (organ or limb ischemia or rupture) type B thoracic aortic dissection;
- Traumatic descending aortic tears or rupture.

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 aortic dissection to be **investigational.***

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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. The Gore TAG®‡ endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for "≥2 cm non-aneurysmal aorta proximal and distal to the aneurysm" and an "aortic inner diameter of 23-37 mm."The Talent™‡ Thoracic Stent Graft System is approved by FDA for "non-aneurysmal aortic proximal and distal neck lengths ≥20 mm" and a "non-aneurysmal aortic diameter in the range of 18-42 mm." The Zenith TX2®‡ device is approved by FDA for nonaneurysmal aortic segments "of at least 25 mm in length" and a "diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm."

Background/Overview

Thoracic Aortic Aneurysms

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

Treatment

Indications for the elective surgical repair of aortic aneurysms are based on estimates of the prognosis of the untreated aneurysm balanced against the morbidity and mortality of the intervention. The prognosis of Thoracic Aortic Aneurysm (TAA) is typically reported regarding the risk of rupture according to size and location (ie, the ascending or descending or thoracoabdominal aorta). While several studies have estimated the risk of rupture of untreated aneurysms, these studies

have excluded patients who underwent surgical repair; therefore, the true natural history of thoracic aneurysms is unknown. Clouse et al (1998) performed a population-based study of TAA diagnosed in Minnesota, between 1980 and 1994. A total of 133 patients were identified; the primary clinical 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 complications, resulting in paraparesis or paraplegia. The operative mortality of surgical repair of aneurysm of the descending and thoracoabdominal aorta is estimated at 6% to 12% and 10% to 15%, respectively, while mortality associated with emergent repair is considerably higher. In elective cases, predictors of operative mortality include renal insufficiency, increasing age, symptomatic aneurysm, the presence of dissection, and other comorbidities (eg, cardiopulmonary or cerebrovascular disease). The risk of paraparesis or paraplegia is estimated at 3% to 15%. Thoracoabdominal aneurysms, larger aneurysms, the presence of dissection, and diabetes are predictors of paraplegia. A number of surgical adjuncts have been explored to reduce the incidence of spinal cord ischemia, including distal aortic perfusion, cerebrospinal fluid drainage, hypothermia with circulatory arrest, and evoked potential monitoring. However, the optimal protective strategy is still uncertain.

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

reserve when the thoracic aneurysm measures from 5.5 to 6 cm in diameter or patients with smaller symptomatic aneurysms.

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

Treatment
Type A dissections are usually treated surgically, while type B dissections are usually treated medically, with surgery indicated for serious complications, such as visceral ischemia, impending rupture, intractable pain, or sudden reduction in aortic size. It has been proposed that endovascular therapy can repair the latter group of dissections by redirecting flow into the true lumen. The success of endovascular stent grafts of abdominal aortic aneurysms has created interest in applying the same technology to the aneurysms and dissections of the descending or thoracoabdominal aorta.

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

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

also lead to rupture. Penetrating ulcers can occur in widespread atherosclerotic disease and lead to aortic rupture.

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

Thoracic Endovascular Aneurysm Repair
TEVAR is an alternative to open surgery. TEVAR has been proposed for prophylactic treatment of aneurysms that meet criteria for surgical intervention, as well as for patients in need of emergency surgery for rupture or complications related to dissection. The standard open surgery technique for TAA is open operative repair with graft replacement of the diseased segment. This procedure requires a lateral thoracotomy, use of cardiopulmonary bypass, lengthy surgical procedures, and is associated with a variety of peri- and postoperative complications, with spinal cord ischemia, considered the most devastating.

TEVAR is performed through a small groin incision to access the femoral artery, followed by delivery of catheters across the diseased portion of the aorta. A tubular stent graft composed of fabric and metal is then deployed under fluoroscopic guidance. The stent graft is then fixed to the proximal and distal portions of the aorta. Approximately 15% of patients do not have adequate femoral access; for them, the procedure can be performed using a retroperitoneal approach.

Potential complications of TEVAR are bleeding, vascular access site complications, spinal cord injury with paraplegia, renal insufficiency, stroke, and cardiopulmonary complications. Some of these complications are similar to those encountered with open repair (eg, paraplegia, cardiopulmonary events), and others are unique to TEVAR (eg, access site complications).

Outcome Measures
Controlled trials of specific patient groups treated with specific procedures are required to determine whether endovascular approaches are associated with equivalent or improved outcomes compared

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

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

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

PMA: premarket approval.

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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 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 Relay®‡ Thoracic Stent-Graft with Plus Delivery System was approved by the FDA through the PMA process for the endovascular repair of fusiform aneurysms and saccular aneurysms or penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:

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

The Valiant™‡ Thoracic Stent Graft with the Captivia®‡ Delivery System was approved by the FDA for isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers, and/or isolated hematomas, but not dissections. Indicated aortic diameter is 18 to 42 mm for aneurysms and penetrating ulcers, and 18 to 44 mm for blunt traumatic injuries. In 2014, the FDA expanded the indication for this graft and delivery system to include all lesions of the descending thoracic aorta, including type B dissections. The Valiant graft is intended for the

endovascular repair of all lesions of the descending aorta in patients having appropriate anatomy, including:

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

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

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

FDA product code: MIH.

Rationale/Source

Thoracic endovascular aneurysm repair (TEVAR) involves the percutaneous placement of a stent graft in the descending thoracic or thoracoabdominal aorta. It is a less invasive alternative 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 to medical therapy for treating thoracic aortic aneurysms or thoracic aorta dissections.

For individuals who have type B (descending) thoracic aortic aneurysms who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. The available nonrandomized comparative studies have consistently reported reduced short-term mortality and morbidity compared with surgical repair. Although these types of studies are subject

to selection bias and other methodologic limitations, the consistency of the findings of equivalent or reduced short-term mortality and fewer early complications across populations with different characteristics supports the conclusion that TEVAR is a safer procedure in the short-term. The likely short-term benefits of TEVAR are mitigated by less favorable longer term outcomes, but longer term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

the available nonrandomized studies are high, raising uncertainty about results. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Clinical input obtained in 2011 demonstrated support for the use of TEVAR for complicated type B dissections and, in certain cases, for traumatic thoracic aortic injury and rupture.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

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

Practice Guidelines and Position Statements

American College of Cardiology Foundation et al

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 (see Table 2).

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

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

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

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 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02622542	A Randomized Controlled Comparative Study on Effectiveness of Endovascular Repair Versus Best Medical Therapy for Acute Uncomplicated Type B Aortic Dissection	436	Dec 2027
NCT02735720	The CardiOvascular Remodeling Following Endovascular Aortic Repair (CORE) Study	24	Jun 2021
Unpublished			
NCT02010892	Effective Treatments for Thoracic Aortic Aneurysms (ETTAA Study): A Prospective Cohort Study	2200	Jul 2019

NCT: national clinical trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Endovascular Stent Grafts for Disorders of the Thoracic Aorta", 7.01.86, June 2020.
2. Clouse WD, Hallett JW, Jr., Schaff HV, et al. Improved prognosis of thoracic aortic aneurysms: a population- based study. JAMA. Dec 9 1998;280(22):1926-1929. PMID 9851478
3. Davies RR, Goldstein LJ, Coady MA, et al. Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size. Ann Thorac Surg. Jan 2002;73(1):17-27; discussion 27-18. PMID 11834007
4. Coady MA, Rizzo JA, Hammond GL, et al. Surgical intervention criteria for thoracic aortic aneurysms: a study of growth rates and complications. Ann Thorac Surg. Jun 1999;67(6):1922-1926; discussion 1953-1928. PMID 10391339
5. Rectenwald JE, Huber TS, Martin TD, et al. Functional outcome after thoracoabdominal aortic aneurysm repair. J Vasc Surg. Apr 2002;35(4):640-647. PMID 11932656

6. Estrera AL, Miller CC, 3rd, Huynh TT, et al. Neurologic outcome after thoracic and thoracoabdominal aortic aneurysm repair. Ann Thorac Surg. Oct 2001;72(4):1225-1230; discussion 1230-1221. PMID 11603441
7. Huynh TT, Miller CC, 3rd, Estrera AL, et al. Thoracoabdominal and descending thoracic aortic aneurysm surgery in patients aged 79 years or older. J Vasc Surg. Sep 2002;36(3):469-475. PMID 12218969
8. Estrera AL, Rubenstein FS, Miller CC, 3rd, et al. Descending thoracic aortic aneurysm: surgical approach and treatment using the adjuncts cerebrospinal fluid drainage and distal aortic perfusion. Ann Thorac Surg. Aug 2001;72(2):481-486. PMID 11515886
9. Safi HJ, Miller CC, 3rd, Subramaniam MH, et al. Thoracic and thoracoabdominal aortic aneurysm repair using cardiopulmonary bypass, profound hypothermia, and circulatory arrest via left side of the chest incision. J Vasc Surg. Oct 1998;28(4):591-598. PMID 9786251
10. Safi HJ, Subramaniam MH, Miller CC, et al. Progress in the management of type I thoracoabdominal and descending thoracic aortic aneurysms. Ann Vasc Surg. Sep 1999;13(5):457-462. PMID 10466987
11. van Dongen EP, Schepens MA, Morshuis WJ, et al. Thoracic and thoracoabdominal aortic aneurysm repair: use of evoked potential monitoring in 118 patients. J Vasc Surg. Dec 2001;34(6):1035-1040. PMID 11743557
12. Webb TH, Williams GM. Thoracoabdominal aneurysm repair. Cardiovasc Surg. Oct 1999;7(6):573-585. PMID 10519663
13. Moulakakis KG, Mylonas SN, Dalainas I, et al. Management of complicated and uncomplicated acute type B dissection. A systematic review and meta-analysis. Ann Cardiothorac Surg. May 2014;3(3):234-246. PMID 24967162
14. Food and Drug Administration Summary of Safety and Effectiveness. Valiant Thoracic Stent Graft with the Captivia Delivery System. 2014; http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100040S012b.pdf.
15. Abraha I, Romagnoli C, Montedori A, et al. Thoracic stent graft versus surgery for thoracic aneurysm. Cochrane Database Syst Rev. Jun 06 2016(6):CD006796. PMID 27265222
16. Makaroun MS, Dillavou ED, Kee ST, et al. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. J Vasc Surg. Jan 2005;41(1):1-9. PMID 15696036
17. Makaroun MS, Dillavou ED, Wheatley GH, et al. Five-year results of endovascular treatment with the Gore TAG device compared with open repair of thoracic aortic aneurysms. J Vasc Surg. May 2008;47(5):912-918. PMID 18353605

18. Fairman RM, Criado F, Farber M, et al. Pivotal results of the Medtronic Vascular Talent Thoracic Stent Graft System: the VALOR trial. J Vasc Surg. Sep 2008;48(3):546-554. PMID 18572352
19. Fairman RM, Tuchek JM, Lee WA, et al. Pivotal results for the Medtronic Valiant Thoracic Stent Graft System in the VALOR II trial. J Vasc Surg. Nov 2012;56(5):1222-1231 e1221. PMID 22832267
20. Matsumoto AH, Angle JF, Secic M, et al. Secondary procedures following thoracic aortic stent grafting in the first 3 years of the VALOR test and VALOR II trials. J Vasc Interv Radiol. May 2014;25(5):685-692 e685. PMID 24529546
21. Matsumura JS, Cambria RP, Dake MD, et al. International controlled clinical trial of thoracic endovascular aneurysm repair with the Zenith TX2 endovascular graft: 1-year results. J Vasc Surg. Feb 2008;47(2):247-257; discussion 257. PMID 18241743
22. Matsumura JS, Melissano G, Cambria RP, et al. Five-year results of thoracic endovascular aortic repair with the Zenith TX2. J Vasc Surg. Jul 2014;60(1):1-10. PMID 24636714
23. Brunkwall J, Kasprzak P, Verhoeven E, et al. Endovascular repair of acute uncomplicated aortic type B dissection promotes aortic remodelling: 1 year results of the ADSORB trial. Eur J Vasc Endovasc Surg. Sep 2014;48(3):285-291. PMID 24962744
24. Fattori R, Montgomery D, Lovato L, et al. Survival after endovascular therapy in patients with type B aortic dissection: a report from the International Registry of Acute Aortic Dissection (IRAD). JACC Cardiovasc Interv. Aug 2013;6(8):876-882. PMID 23968705
25. Boufi M, Patterson BO, Loundou AD, et al. Endovascular Versus Open Repair for Chronic Type B Dissection Treatment: A Meta-Analysis. Ann Thorac Surg. May 2019; 107(5): 1559-1570. PMID 30481516
26. Thrumurthy SG, Karthikesalingam A, Patterson BO, et al. A systematic review of mid-term outcomes of thoracic endovascular repair (TEVAR) of chronic type B aortic dissection. Eur J Vasc Endovasc Surg. Nov 2011;42(5):632-647. PMID 21880515
27. Nienaber CA, Kische S, Akin I, et al. Strategies for subacute/chronic type B aortic dissection: the Investigation Of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial 1-year outcome. J Thorac Cardiovasc Surg. Dec 2010;140(6 Suppl):S101-108; discussion S142-S146. PMID 21092774
28. Nienaber CA, Kische S, Rousseau H, et al. Endovascular repair of type B aortic dissection: long-term results of the randomized investigation of stent grafts in aortic dissection trial. Circ Cardiovasc Interv. Aug 2013;6(4):407- 416. PMID 23922146

29. Pang D, Hildebrand D, Bachoo P. Thoracic endovascular repair (TEVAR) versus open surgery for blunt traumatic thoracic aortic injury. Cochrane Database Syst Rev. Sep 25 2015;9(9):CD006642. PMID 26407315
30. Jonker FH, Trimarchi S, Verhagen HJ, et al. Meta-analysis of open versus endovascular repair for ruptured descending thoracic aortic aneurysm. J Vasc Surg. Apr 2010;51(4):1026-1032. PMID 20347700
31. Lee WA, Matsumura JS, Mitchell RS, et al. Endovascular repair of traumatic thoracic aortic injury: clinical practice guidelines of the Society for Vascular Surgery. J Vasc Surg. Jan 2011;53(1):187-192. PMID 20974523
32. Ultee KHJ, Zettervall SL, Soden PA, et al. The impact of endovascular repair on management and outcome of ruptured thoracic aortic aneurysms. J Vasc Surg. Aug 2017;66(2):343-352 e341. PMID 28366304
33. Elkbuli A, Dowd B, Spano PJ, et al. Thoracic Endovascular Aortic Repair Versus Open Repair: Analysis of the National Trauma Data Bank. J Surg Res. Jan 2020; 245: 179-182. PMID 31421360
34. Scalea TM, Feliciano DV, DuBose JJ, et al. Blunt Thoracic Aortic Injury: Endovascular Repair Is Now the Standard. J Am Coll Surg. Apr 2019; 228(4): 605-610. PMID 30630086
35. Yamaguchi T, Nakai M, Sumita Y, et al. Editor's Choice - Endovascular Repair Versus Surgical Repair for Japanese Patients With Ruptured Thoracic and Abdominal Aortic Aneurysms: A Nationwide Study. Eur J Vasc Endovasc Surg. Jun 2019; 57(6): 779-786. PMID 30837104
36. Vallabhajosyula P, Gottret JP, Bavaria JE, et al. Endovascular repair of the ascending aorta in patients at high risk for open repair. J Thorac Cardiovasc Surg. Feb 2015;149(2 Suppl):S144-150. PMID 25218530
37. Roselli EE, Idrees J, Greenberg RK, et al. Endovascular stent grafting for ascending aorta repair in high-risk patients. J Thorac Cardiovasc Surg. Jan 2015;149(1):144-151. PMID 25312226
38. Appoo JJ, Herget EJ, Pozeg ZI, et al. Midterm results of endovascular stent grafts in the proximal aortic arch (zone 0): an imaging perspective. Can J Cardiol. Jun 2015;31(6):731-737. PMID 25882336
39. Hiratzka LF, Bakris GL, Beckman JA, et al. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the diagnosis and management of patients with thoracic aortic disease. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular

Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. J Am Coll Cardiol. Apr 6 2010;55(14):e27-e129. PMID 20359588

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09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review
09/22/2005	Quality Care Advisory Council approval
05/03/2006	Medical Director review
05/17/2006	Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/07/2007	Medical Director review
11/15/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. Coverage eligibility unchanged.
11/12/2009	Medical Policy Committee approval
11/18/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Eligible for coverage statements reformatted to clarify the intent that use is for specific types of aneurysms without dissection, for complicated Type B dissections and for traumatic aortic injury (when specific conditions are met). Added a *Note* to the coverage section for clarification.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Policy # 00181
Original Effective Date: 09/22/2005
Current Effective Date: 05/10/2021

11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. Eligible for coverage indication added for acute rupture of the thoracic aorta.
11/06/2014	Medical Policy Committee review
11/21/2014	Medical Policy Implementation Committee approval. Title changed from "Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections" to "Endovascular Stent Grafts for Disorders of the Thoracic Aorta". Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Updated INV statement.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2018	Coding update
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Moved the *"Note"* from the coverage section to a newly created Policy Guidelines section.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. Coverage revised for clarity. Coverage intent and eligibility unchanged.
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.

Next Scheduled Review Date: 04/2022

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 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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:

Code Type	Code
CPT	33880, 33881, 33883, 33884, 33886, 75956, 75958, 75959
HCPCS	No codes
ICD-10 Diagnosis	I71.00-I71.01, I71.1-I71.8, S25.101A-S25.109A, S25.11A-S25.119A, S25.121A-S25.129A, S25.191A-S25.199A

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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

‡ 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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.