BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections

Policy #: 637
Latest Review Date: August 2024
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after June 23, 2021:

Blue Advantage will treat **endovascular stent grafts using devices approved by U.S. Food and Drug Administration (FDA)** as a **covered benefit** for the following conditions:

- Descending thoracic aortic aneurysms used according to FDA-approved specifications
- Acute, complicated (organ or limb ischemia or rupture) type B thoracic aortic dissection.
- Descending thoracic aortic tears or rupture.

Blue Advantage will treat **endovascular stent grafts** as a **non-covered benefit** and as **investigational** for the treatment of descending aortic disorders that do not meet the above criteria.

Blue Advantage will treat **endovascular stent grafts** as a **non-covered benefit** and as **investigational** for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Thoracic Aortic Aneurysms

Aortic aneurysms are arterial dilations that are associated with age, atherosclerosis, and hypertension, as well as some congenital connective tissue disorders. The likelihood of significant sequelae of aortic aneurysm is dependent on location, size, and underlying disease state. Left untreated, these aneurysms tend to enlarge over time, increasing the risk of rupture or dissection. Of greatest concern is the tendency for aortic aneurysms to rupture, with severe consequences including death. Another significant adverse occurrence of aortic aneurysm is aortic dissection, in which an intimal tear permits blood to enter the potential space between the

intima and the muscular wall of the aorta. Stable dissections may be managed medically; however, dissections 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 in terms of the risk of rupture according to size and location, i.e., the ascending or descending or thoracoabdominal aorta. While several studies have estimated the risk of rupture of untreated aneurysms, these studies have excluded patients who underwent surgical repair; therefore, the true natural history of thoracic aneurysms is unknown. Clouse et al (1998) performed a population-based study of TAA diagnosed in Olmstead County, Minnesota, between 1980 and 1994. 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. A total of 304 patients were dissection-free at presentation; their natural history was followed up for rupture, dissection, and death. Patients were excluded from analysis once the operation occurred. Not surprisingly, the authors reported that aneurysm size had a profound impact on outcomes. For example, based on their modeling, a patient with an aneurysm exceeding 6 cm in diameter can expect a yearly rate of rupture or dissection of at least 6.9% and a death rate of 11.8%. In a previous report, the authors suggested surgical intervention of a descending aorta aneurysm if its diameter measured 6.5 cm.

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

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

Thoracic Aortic Dissection

Aortic dissection can be subdivided into Type A, which involves the aortic arch, and Type B, which is confined to the descending aorta. 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 the table below.

Category	Description
Uncomplicated	• No rupture • No malperfusion • No high-risk features
Complicated	• Rupture • Malperfusion
High risk	• Refractory pain • Refractory hyperfusion • Bloody plural effusion • Aortic diameter >40mm • Radiographic only malperfusion • Readmission • Entry tear: lesser curve location • False lumen diameter >22mm
Chronicity (time elapsed since the onset of symptoms)	• Hyperacute (<24 hours) • Acute (1 to 14 days) • Subacute (15 to 90 days) • Chronic (>90 days)

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

As noted, type A dissections (involving the ascending aorta) are treated surgically. There is more controversy regarding the optimal treatment of Type B dissections (i.e., limited to the descending aorta). In general, chronic, stable Type B dissections are managed medically, although some surgeons 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.

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 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.

KEY POINTS:

The most recent literature review was updated through July 1, 2024.

Summary of Evidence

For individuals who have type B (descending) thoracic aortic aneurysms who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, treatment-related morbidity, and treatment-related mortality. The available nonrandomized comparative studies consistently report reduced short-term morbidity and mortality compared with surgical repair. Although these types of studies are subject to selection bias and other methodologic limitations, the consistency of the findings of equivalent or reduced short-term mortality and fewer early complications across populations with different characteristics support the conclusion that TEVAR is a safer procedure in the short term. The likely short-term benefits of TEVAR are mitigated by less

favorable longer term outcomes, but longer term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery. The evidence is sufficient to determine qualitatively that the technology results in 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 OS, 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 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 descending aortic tears or rupture who receive endovascular repair, the evidence includes non-randomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, treatment-related morbidity, and treatment-related mortality. 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 outcome.

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

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. The guideline included the recommendations regarding thoracic aortic disorders below.

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

Recommendation	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 considereda	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; TAAA: 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. The guideline included the recommendations regarding thoracic aortic disorders below.

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 thoracic aortic aneurysms. The guideline included the following recommendations:

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 5.5cm 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 or life, with consideration of more frequent imaging if an endo leak or other abnormality of concern is detected at 1 month	1	B

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

U.S. Preventive Services Task Force Recommendations
Not applicable

KEY WORDS:

Aneurysm, Thoracic Aorta, Endovascular Stent, Stents, Thoracic Aortic Aneurysm, Endovascular Graft, GORE TAG® Thoracic Endoprosthesis, Zenith TX2® TAA Endovascular Graft, Talent™ Thoracic Stent Graft System, TEVAR, thoracic aneurysm, TAA, aortic aneurysm

APPROVED BY GOVERNING BODIES:

A number of endovascular grafts are approved for use in thoracic aortic aneurysms (TAAs).

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® DeliverySystem	Medtronic Vascular	Apr 2011	P100040

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 23to 37 mm, and 2 cm or more nonaneurysmal aorta proximal and distal to the aneurysm. In 2012, the FDA expanded the indication for the Gore TAG® system to include isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers, and/or isolated hematomas, but do not include dissections. Indicated aortic inner diameter is 16 to 42 mm, with 20 mm or more of nonaneurysmal aorta distal and proximal to the lesion.

The Zenith TX2® TAA Endovascular Graft was approved by the FDA through the premarket approval (PMA) process for the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta. Indicated aortic inner diameter ranges from 24 to 38 mm.

The Talent™ Thoracic Stent Graft System was approved by the FDA through the PMA process for the endovascular repair of fusiform and saccular aneurysms or penetrating ulcers of the descending thoracic aorta. Indicated aortic inner diameter ranges from 18 to 42 mm. The Talent Thoracic Stent Graft System was discontinued by the manufacturer and replaced with the Valiant™ Thoracic Stent Graft System.

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

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

The Relay®Pro system is indicated for treatment of all lesions of the descending thoracic aorta, 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 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

33880	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33881	; not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33883	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension

33884	; each additional proximal extension (list separately in addition to code for primary procedure)
33886	Placement of distal extension prosthesis(s) delayed after endovascular repair of descending thoracic aorta
33889	Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral
33891	Bypass graft, with other than vein, transcervical retropharyngeal carotid-carotid, performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision
75956	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision, and interpretation
75957	; not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision, and interpretation
75958	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption), radiological supervision, and interpretation
75959	Placement of distal extension prosthesis(s) delayed after endovascular repair of descending thoracic aorta, as needed, to level of celiac origin, radiological supervision, and interpretation

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POLICY HISTORY:

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Medical Policy Group, June 2017
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Medical Policy Group, June 2018
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Medical Policy Group, June 2021
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UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, August 2024: Annual update. Removed policy statements effective for dates of service prior to June 23, 2021.
