BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Endovascular Stent Grafts for Thoracic Aortic Aneurysms or Dissections

Policy #: 637
Category: Surgery

Latest Review Date: June 2020
Policy Grade: B

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:

Effective for dates of service on and after June 15, 2017:

Blue Advantage will treat **endovascular stent grafts** using devices approved by the FDA according to the approved specifications as a **covered benefit** for **the treatment of descending thoracic aortic aneurysms without dissection.**

Blue Advantage will treat **endovascular stent grafts** using devices approved by the FDA according to the approved specifications as a **covered benefit** for the **treatment of acute, complicated (organ or limb ischemia or rupture) Type B thoracic aortic dissection.**

Blue Advantage will treat **endovascular stent grafts** as a **covered benefit** for the **treatment of rupture of the descending thoracic aorta.**

Blue Advantage will treat **endovascular stent grafts** as a **non-covered benefit** and as **investigational** for the treatment of thoracic lesions, including but not limited to **thoracic aortic arch aneurysms, acute, uncomplicated Type B thoracic aortic dissection, and chronic Type B aortic dissection.**

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 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.

Treatment
Type A dissections (involving the aortic arch) 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.

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. 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 morbidity and 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 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 March 24, 2020.

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 lends support to the conclusion that TEVAR is a safer procedure in the short term. The likely short-term benefits of TEVAR are mitigated by longer term outcomes that are less favorable for TEVAR, 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 a meaningful improvement in the net health outcome.

For individuals who have Type B aortic dissections who receive endovascular repair, the evidence includes randomized controlled trials (RCTs), systematic reviews and non-randomized comparative studies. Relevant outcomes are overall survival, morbid events, treatment-related morbidity, and treatment-related mortality.

- For acute 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 suggests 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. The evidence is insufficient to determine the effects of the technology on health outcomes.
- For acute uncomplicated Type B dissections, 1 RCT 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 include a high rate of failure of imaging follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.
- For chronic Type B dissections, the evidence from 1 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 post-procedure. 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 non-randomized comparative studies and systematic reviews. Relevant outcomes are overall survival, morbid events, treatment-related morbidity, and treatment-related mortality. For traumatic thoracic aortic injury and rupture, nonrandomized comparative data have suggested a benefit for TEVAR in reducing periprocedural mortality and morbidity. It is expected that RCTs will be difficult to perform for this indication due to its emergent nature.

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 Foundation, American Heart Association, et al

In 2010, a joint task force published guidelines on the diagnosis and management of descending thoracic and thoracoabdominal aortic aneurysms. The task force consisted of the American College of Cardiology Foundation, American Heart Association, 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. The task force offered the following Class I recommendations:

- 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 (*Level of Evidence: 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 (*Level of Evidence: 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 (*Level of Evidence: 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. (470) (*Level of Evidence: B*)

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).

In March 2005, the GORE TAG® Thoracic Endoprosthesis (W.L. Gore and Associates, Inc. Flagstaff, AZ) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process 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 23–37 mm, and equal to or greater than 2 cm non-aneurysmal aorta proximal and distal to the aneurysm. In January 2012, FDA granted an expanded 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.

In May 2008, the Zenith TX2® TAA Endovascular Graft (Cook Incorporated, Bloomington, IN) 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 is in the range of 24-38 mm.

In September 2015, the Zenith Alpha™ Thoracic Endovascular Graft (Cook) was approved by the FDA through the PMA process.

In June 2008, the Talent™ Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, CA) was approved by the FDA through the PMA process for the endovascular repair of fusiform and saccular aneurysms/penetrating ulcers of the descending thoracic aorta. Indicated aortic inner diameter is in the range of 18–42 mm.

In September 2012, Relay® Thoracic Stent-Graft with Plus Delivery System (Bolton Medical, Sunrise, FL) was approved by FDA through the PMA process for the endovascular repair of fusiform aneurysms and saccular aneurysms/ penetrating atherosclerotic ulcers in the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories
- Nonaneurysmal aortic neck diameter in the range of 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.

In 2011, the Valiant™ Thoracic Stent Graft with the Captivia® Delivery System (Medtronic Vascular, Santa Rosa, CA) was approved by FDA through the PMA process for isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers, and/or isolated hematomas, but not including dissections. Indicated aortic diameter is 18 to 42 mm for aneurysms and penetrating ulcers, and 18 to 44 mm for blunt traumatic injuries. In January 2014, FDA-approved indications for the Valiant™ Thoracic Stent Graft with the Captivia® Delivery System were expanded 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 that is compatible with vascular access techniques, devices, and/or accessories;
- Nonaneurysmal aortic diameter in the range of 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 20 mm or more (fusiform and saccular aneurysms/penetrating ulcers), and landing zone 20 mm or more proximal to the primary entry tear (BTAI, dissection). The proximal extent of the landing zone must not be dissected.

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

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.

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:

Adopted for Blue Advantage, February 2017.
Available for comment February 22 – April 7, 2017
Medical Policy Group, June 2017
Available for comment June 17 through August 1, 2017
Medical Policy Group, June 2018
Medical Policy Group, May 2019
Medical Policy Group, June 2020
