Endovascular/Endoluminal Repair of Aortic Aneurysms, Aortoiliac Disease, Aortic Dissection and Aortic Transection

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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.

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 the use of a U.S. Food and Drug Administration (FDA) approved fenestrated and branched endovascular/endoluminal stent graft device (including physician-modified endovascular grafts [PMEGs]) to be **eligible for coverage**** for repair of juxtarenal and thoraco-abdominal aortic aneurysms when the individual is not a candidate for open surgical repair due to medical comorbidities.

When Services May Be Eligible for Coverage

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

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

Based on review of available data, the Company may consider the use of U.S. Food and Drug Administration (FDA) approved endovascular/endoluminal stent graft devices for individuals to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for the use of U.S. Food and Drug Administration (FDA) approved endovascular/endoluminal stent graft devices for individuals when **ANY** of the following criteria are met:

- Abdominal aortic aneurysm; **OR**
- Aortoiliac aneurysm; **OR**
- Descending thoracic aortic aneurysm; **OR**
- Complicated Type B descending thoracic aortic dissection when distal to the aortic arch; **OR**
- Treatment of traumatic thoracic aortic transection.

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 non-FDA approved endovascular/endoluminal stent graft devices to be **investigational.***

Based on review of available data, the Company considers the use of endovascular/endoluminal stent graft devices for all other indications not noted above to be **investigational*** including, but not limited to, the treatment of thoracic aortic arch aneurysms and Type A aortic dissections.
to be **investigational.***

The use of an FDA approved fenestrated and branched endovascular/endoluminal stent graft device (including physician-modified endovascular grafts [PMEGs]) when patient selection criteria are not met is considered to be **investigational.***

Background/Overview

Abdominal Aortic Aneurysms (AAA)

An aneurysm is an abnormal "bulging" of a vessel, usually due to a congenital or acquired weakness or thinning of the vessel wall. Aortic aneurysms are commonly classified according to their anatomical location. While thoracic aortic aneurysms (TAA) involve the ascending aorta, aortic arch or descending aorta, abdominal aortic aneurysms (AAA) affect the part of the aorta in the abdominal cavity.

AAA is a relatively common condition in older individuals, with a prevalence of 8% in individuals over 65 years of age. Major complications of AAA include rupture and dissection or splitting of the walls of the aorta. TAA may be caused by the effects of atherosclerosis, high blood pressure, or in rare cases syphilis or tuberculosis. It can also be inherited via connective tissue disorders, such as Marfans or Ehlers Danlos Syndromes. While both TAA and AAA can be surgically repaired using stents and grafts, these open procedures are associated with considerable morbidity and mortality. Endovascular repair (EVAR) was developed to provide a minimally invasive approach, using a catheter inserted through a small groin incision to place the stent/graft across the aneurysm site.

Rationale/Source

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

Abdominal Aortic Aneurysms (AAA)

The use of an endovascular/endoluminal stent graft for the repair of an abdominal or an aortoiliac aneurysm is considered a medically acceptable alternative to open surgical repair for some aneurysms. A variety of devices have received U.S. Food and Drug Administration (FDA) clearance, including both straight and bifurcated grafts that extend into the iliac arteries. Fenestrated grafts have also been evaluated. These grafts are designed with openings in the wall that can be placed across the renal or celiac arteries while still protecting vessel patency. In addition, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal. Fenestrated and branched stent grafts were designed to extend the proximal sealing zone from the infrarenal segment to the juxta- and suprarenal aorta, thereby circumventing the limitation of short or absent aortic necks. When the need is to preserve flow to a visceral artery, due to the position of the aortic aneurysm, the fenestrated graft is being proposed for use. When the need is to provide flow to a visceral artery where the aortic aneurysm also involves the visceral artery, branched stent grafts are being studied for this use (Amiot, 2010; Chisci, 2009; Greenberg, 2004; Greenberg, 2009; Lyden, 2008; Muhs, 2006; Ricotta, 2008; Verhoeven, 2010). Both fenestrated and branched endovascular/endoluminal stent graft devices can be modified, as needed, to accommodate the

individual's specific anatomy. This is referred to as physician-modified endovascular grafts (PMEGs), which were described by a practicing physician as, "PMEG therapy is used to preserve branch vessels when used in the treatment of patients with elective, symptomatic, or ruptured juxtarenal aortic aneurysms." The Society for Vascular Surgery (SVS) announced in 2011 that, "A recent study showed that PMEGs are an effective method of treating juxtarenal aortic aneurysms in patients who are considered to be unsuitable for open surgical repair" (Zettervall, 2021; NCT01538056).

In April 2012, the FDA granted clearance for the first fenestrated endovascular device for use in the U.S. The Zenith®‡ Fenestrated AAA Endovascular Graft with the adjunctive Zenith Alignment Stent (Cook Medical, Inc., Bloomington, IN) was cleared for the endovascular treatment of abdominal aortic or aorto-iliac aneurysms having morphology suitable for endovascular repair, subject to FDA-stipulated anatomic specifications. The Zenith Alignment Stent is indicated for use as an adjunct to the Zenith Fenestrated AAA Endovascular Graft, "To secure positive alignment of fenestrations or scallops with the orifice of aortic branch vessels having diameters ranging from 3 to 8 mm." This FDA clearance is contingent upon manufacturer submission of periodic safety and effectiveness reports, results of a post-approval study to be conducted to provide long-term outcomes data on stent graft recipients, and a report of an observational, prospective, single-arm registry study designed to evaluate the physician training program provided by the manufacturer (FDA, 2012).

The FDA clearance of the Zenith Fenestrated Graft was based on 6-month results from a nonrandomized, multi-center, 2-arm study that enrolled 42 individuals with AAA and a short infrarenal aortic neck. One study arm consisted of investigational subjects implanted with the Zenith Fenestrated AAA Endovascular Graft and the second arm consisted of historical, case-matched controls that had been previously treated with the standard Zenith AAA Endovascular Graft. The study results for the primary endpoint, 6-month treatment success, were explored in subjects treated with the Zenith Fenestrated AAA Endovascular Graft and in matched subjects treated with the standard Zenith AAA Endovascular Graft. The study additionally provided for assessment of morbidity, mortality, aneurysm size change, endoleak, migration, device integrity, and secondary interventions. Of the 42 subjects enrolled in the clinical study, 40 were evaluable for the primary endpoint analysis (2 individuals were lost to follow-up). The 6-month treatment success was 97.5% in the fenestrated endovascular treatment group compared to 95% in the matched Zenith AAA cohort. One Zenith fenestrated recipient experienced a major adverse event within 30 days (bowel

ischemia, which resolved with antibiotics and IV fluids). No aneurysm ruptures or conversions to open repair were reported within 30 days of the initial implant; there was one death in the Zenith fenestrated group for unknown causes, which was attributed to the AAA. Pre-specified renal adverse events included renal infarct, renal insufficiency, renal failure requiring dialysis, and occlusion of a fenestrated renal vessel. There were five instances of renal infarct (none were associated with a clinical event), each of which occurred in a study subject with some degree of either thrombus or calcification in the seal zone, (as well as a history of infarct and coverage of an accessory renal vessel in one). Two of 3 subjects with renal insufficiency in the Zenith fenestrated group had renal dysfunction prior to treatment, which was considered unrelated to the AAA-repair, 1 of which required dialysis. Two subjects developed occlusion of a fenestrated renal vessel (neither was associated with graft migration), 1 of which had evidence of fenestration stent compression (from suboptimal stent placement in the mid/upper portion of the fenestration) that required reintervention. There were no reports of Type I or Type III endoleak, and the only reports of aneurysm growth (n=2) occurred with a Type II endoleak.

There were two reports of migration, both with evidence of disease progression at follow-up (without aneurysm pressurization), one of which had associated fenestration stent compression requiring secondary intervention. One subject was noted to have fracture of a fenestration stent, as well as the seal stent on the fenestrated graft, neither of which resulted in endoleak, a clinical renal event, or the need for secondary intervention. The majority of subjects who underwent reintervention following treatment with the Zenith fenestrated graft (n=7 of 11) did so for renal stenosis. There was evidence of fenestration stent deformation in 2 of 7 subjects that underwent reintervention for renal stenosis. The investigators concluded that the outcomes were reasonable for the subjects requiring treatment with a fenestrated endovascular graft. As expected, there were more renal events with the fenestrated device, as compared to the standard version of the endovascular graft. The findings of this study were limited by small size, use of nonrandomized historic controls and short follow-up (6 months). It was noted that the risk for renal events could be diminished, in future, with proper candidate selection and follow-up. Study subjects from this study were followed for up to 5 years (Greenberg, 2009). Additional ongoing studies are anticipated to provide more long-term outcomes data in future (NCT01652235).

In 2021, final 5-year results of the United States Zenith Fenestrated prospective multicenter study for juxtarenal abdominal aortic aneurysms were published (Oderich, 2021). This prospective,

nonrandomized multi-center study was designed to evaluate the Zenith Fenestrated AAA Endovascular Graft for juxtarenal AAAs. Sixty-seven subjects (54 male, mean age 74 ± 8 years) were prospectively enrolled at 14 U.S. centers from 2005 to 2012. Fenestrated stent grafts were used in subjects with infrarenal aortic neck lengths of 4 to 14 mm to target 178 renal-mesenteric arteries with a mean of 2.7 vessels per subject. At 5 years, 42 of the 67 trial participants completed the final study follow-up, with clinical examination obtained in 41 and computed tomography (CT) imaging in 39. Outcomes adjudicated by a clinical events committee included all-cause and aneurysm-related mortality, major adverse events, renal stent occlusion/stenosis, renal function changes and renal infarcts, aneurysm sac enlargement (> 5 mm), device migration (≥ 10 mm), type I/III endoleak, and secondary interventions. Median follow-up was 59.8 months (range, 0.1-67.5 months). There were 7 deaths, including 1 (1.5%) within 30 days (due to bowel ischemia and considered procedure-related) and 6 beyond 30 days (not procedure-related in 5, indeterminate in 1). At 5 years, freedom from all-cause mortality was 88.8 ± 4.2% and freedom from aneurysm-related mortality was 96.8 ± 2.3%. There were no aneurysm ruptures or conversions to open surgery. Of the 129 renal arteries targeted by fenestrations, 5 (4%) occluded and 14 (11%) developed in-stent stenosis. Treatment included redo stenting/angioplasty in 13 vessels, renal artery bypass in 2 vessels, and failed thrombectomy in 1 vessel. Primary and secondary renal target patency was 82.7 ± 4.1% and 95.7 ± 2.1% at 5 years, respectively. Dialysis was required in 1 subject who had pre-existing chronic kidney disease. During the 5 years, there was 1 type IA endoleak (1.5%), 1 type IB endoleak (1.5%), 2 device migrations (3%), and 4 aneurysm sac enlargements (6%). Overall, 81% of subjects had sac shrinkage at 5 years. Of 20 individuals who underwent secondary interventions, 12 were for renal in-stent stenosis or occlusion, 7 were for endoleak, and 1 was for both indications. Freedom from secondary intervention was 63.5 ± 7.2% at 5 years. There was incomplete 5-year follow-up data for 25 trial participants, due to lack of consent provided for follow-up longer than 2 years in 6 subjects, death in 7 subjects, and withdrawal or loss to follow-up in 12 individuals.

Verhoeven and colleagues (2015) reported experience with endovascular thoracoabdominal aortic aneurysm (TAAA) repair using fenestrated and branched stent grafts over 10 years. Consecutive participants (n=166) were treated with fenestrated and branched stent grafts. Types of TAAA were: type I (n=12, 7.2%), type II (n=50, 30.1%), type III (n=53, 31.9%), type IV (n=41, 24.8%), and type V (n=10, 6%). Fifteen (9%) participants had an acute TAAA (11 contained rupture, 4 symptomatic). A total of 108 (65%) participants were refused for open surgery earlier, and 78 (47%) participants had previously undergone one or more open/endovascular aortic procedures. Technical success was

95% (157/166). Thirty-day operative mortality was 7.8% (13/166), with an in-hospital mortality of 9% (15/166). Perioperative spinal cord ischemia (SCI) was observed in 15 participants (9%), including permanent paraplegia in 2 participants (1.2%). The authors concluded that TAAA fenestrated and branched stent grafts in a high-risk cohort appear safe and effective in the mid-term when performed in high volume centers, although a considerable reintervention rate was also apparent.

In 2016, Li and colleagues performed a systematic review comparing outcomes of fenestrated and chimney techniques to traditional methods used to treat juxtarenal aortic aneurysms (JAAs). Nine fenestrated endovascular aneurysm repair (F-EVAR) cohort studies consisting of 542 JAA subjects and eight chimney endovascular aneurysm repair (CH-EVAR) cohorts with 158 JAA subjects were included in the review. The authors noted that both techniques appeared to be effective for the treatment of JAAs. Long-term durability continues to be assessed.

Patel and colleagues (2016) reported long-term follow-up results from the Endovascular Aneurysm Repair (EVAR) randomized controlled trial (EVAR trial 1), which recruited 1252 individuals from 37 UK hospitals between Sept 1, 1999, and Aug 31, 2004. Subjects were at least 60 years of age, had AAA at least 5.5 cm in diameter, and were determined to be suitable for either conventional endovascular repair (EVAR) or open repair. Randomization occurred 1:1 to either EVAR (n=626) or open repair (n=626). Over a mean of 12.7 years of follow-up, there were 9.3 deaths per 100 person-years in the EVAR group and 8.9 deaths per 100 person-years in the open-repair group. Of note, at 0-6 months post randomization, subjects in the EVAR group had a lower mortality and after 8 years of follow-up, those in the open-repair group had a significantly lower mortality. The higher aneurysm-related mortality in the EVAR group after 8 years was attributed to secondary aneurysm sac rupture. Increased cancer mortality was also observed in the EVAR group. The authors indicated that the results of this study "Needs to be addressed by lifelong surveillance of EVAR and prompt re-intervention if necessary."

The original FDA clearance for conventional EVAR grafts for abdominal aortic aneurysms (AAA) did not require randomized studies. Randomized studies of straight or bifurcated grafts have now been reported that provide additional information in two categories of individuals: those considered candidates for an open repair, and those not considered candidates for an open repair, due to comorbidities. Several devices have received FDA pre-market clearance for the endovascular

treatment of infrarenal abdominal aortic or aorto-iliac aneurysms, subject to FDA-approved labeling indications. These include, but are not limited, to: the AneuRx®‡ (Medtronic, Inc., Santa Rosa, CA); the Ancure®‡ System and the Ancure®‡ Aortoiliac System (Guidant Corp., Menlo Park, CA); the Zenith®‡ AAA Endovascular Graft with the H & L-B One-Shot™‡ Introduction System (Cook, Inc. Bloomington, IN); and the EXCLUDER™‡ (W. L. Gore & Associates, Inc., Flagstaff, AZ).

In 2009, preliminary 2-year results were published for the ongoing Standard Open Surgery Versus Endovascular Repair of Abdominal Aortic Aneurysm (OVER Trial), which is sponsored by the U.S. Department of Veterans Affairs. This is a randomized, multicenter clinical trial of 881 veterans (aged 49 years or greater) from 42 Veterans Affairs Medical Centers who had eligible AAAs. Elective endovascular (n=444) or open (n=437) repair of AAA was performed. The main outcome measures were procedure failure, secondary therapeutic procedures, length of stay, quality of life, erectile dysfunction, and major morbidity/mortality. At the mean follow-up of 1.8 years, perioperative mortality (30 days or inpatient) was lower for endovascular repair (0.5% vs. 3.0%; p=0.004), but there was no significant difference in mortality at 2 years (7.0% vs. 9.8%, p=0.13). Individuals in the endovascular repair group had reduced median procedure time (2.9 vs. 3.7 hours), blood loss (200 vs. 1000 mL), transfusion requirement (0 vs. 1.0 units), duration of mechanical ventilation (3.6 vs. 5.0 hours), hospital stay (3 vs. 7 days), and intensive care unit stay (1 vs. 4 days), but required substantial exposure to fluoroscopy and contrast. There were no differences between the two groups in major morbidity, procedure failure, secondary therapeutic procedures, aneurysm-related hospitalizations, health-related quality of life, or erectile function. However, the authors note that the early advantage of endovascular repair was not offset by increased morbidity or mortality in the first 2 years after repair and that longer-term outcome data are needed to fully assess the relative merits of the two procedures (Lederle, 2009). Longer term follow-up was reported in 2012 in which the previously reported reduction in perioperative mortality with endovascular repair was sustained at 2 years (hazard ratio, 0.63; 95% confidence interval [CI], 0.40 to 0.98; p=0.04) and at 3 years (hazard ratio, 0.72; 95% CI, 0.51 to 1.00; p=0.05) but not thereafter:

> The perioperative survival advantage with endovascular repair was sustained for several years, but rupture after repair remained a concern. Endovascular repair led to increased long-term survival among younger patients but not among older patients, for whom a greater benefit from the endovascular approach had been expected (Lederle, 2012).

Long-term outcomes of the Dutch Randomized Endovascular Aneurysm Repair (DREAM) trial were published in 2010. Six years after randomization, the cumulative survival rates were 69.9% for open repair and 68.9% for EVAR (p=0.97). The cumulative rates of freedom from secondary interventions were 81.9% for open repair and 70.4% for EVAR (p=0.03). The authors concluded that these long-term outcomes data are very similar for both the open and EVAR treated groups with a higher rate of secondary interventions necessary in the EVAR treated group. The authors acknowledge that much larger trials or analysis of existing data are needed to determine selection criteria for those who would most benefit from EVAR procedures (De Bruin, 2010; earlier results: Blankensteijn, 2005).

Additional studies have examined the results of EVAR of ruptured AAA with findings that suggest more favorable morbidity and mortality associated with EVAR but the data is limited by short-term outcomes, potential selection bias and disparate vessel anatomy and disease severity across the treatment arms of the studies. The authors commented that higher volume facilities seem to demonstrate better short-term outcomes (Arya, 2006; Chambers, 2009; Foster, 2010; Giles, 2009; Peppelenbosch, 2006). McPhee (2009) reported that 19% of ruptured AAA treated in the U.S. in 2006 were performed with EVAR and that registry data suggested a lower in-hospital mortality rate with EVAR than with open repair of ruptured AAA.

The Society for Vascular Surgery (SVS) Practice Guidelines issued a document in 2009 entitled, The Care of Patients with an Abdominal Aortic Aneurysm which states that, "Endovascular aneurysm repair (EVAR) has rapidly expanded and is progressively replacing open surgical repair for the treatment of infrarenal AAA." The guideline also states that generally, only aneurysms with adverse neck anatomy not suitable for EVAR undergo standard open surgical repair. The guideline includes the following recommendation:

- Emergent EVAR should be considered for treatment of a ruptured AAA, if anatomically feasible. (Level of recommendation: Strong, Quality of evidence: Moderate.) (Chaikof, 2009).

In 2018, the SVS issued an updated guideline on the care of AAA, which reiterated that open surgery and EVAR are options for aneurysms that meet certain treatment thresholds. The following was noted:

- EVAR is progressively replacing open surgery as the treatment of choice, and accounts for more than half of all elective AAA repairs in the United States.
- Emergent EVAR should be considered for treatment of a ruptured AAA, if anatomically feasible. (Level of recommendation: Strong, Quality of evidence: Moderate).
- EVAR may be considered for high-risk patients unfit for surgical repair. (Level of recommendation: Weak, Quality of evidence: Low).
- For patients with ruptured aneurysm, immediate repair is recommended. (Level of recommendation: Strong, Quality of evidence: High) (Chaikof, 2018).

Descending Thoracic Aortic Aneurysms (TAA)
Thoracic endovascular aortic repair (TEVAR) has also been proposed for the repair of descending thoracic aortic aneurysms (TAA). The first device to receive FDA clearance for this indication (in 2005) was the GORE TAG®‡ Thoracic Endoprosthesis (W. L. Gore and Associates, Inc., Flagstaff, AZ). Similar to the FDA approval of AAA stent grafts, the FDA did not require randomized trials for approval of the GORE TAG device. The FDA based its approval on the results of two comparative case series, using historical and concurrent controls with two different designs of the prosthesis. In the first case series, TAG 99-01, the results of 140 individuals, treated endovascularly, were compared with 94 concurrent and historical controls (Bavaria, 2007; Makaroun, 2005; Wheatley, 2006). The primary outcome was the number of individuals who had one or more major adverse events and the number of individuals that did not experience device related events 12 months post deployment. The number of individuals experiencing greater than or equal to one major adverse event (42%) was significantly lower than the surgical repair control group (77%) at 1-year follow up. Additionally, 4 of 140 individuals (3%) experienced paraplegia or paraparesis vs. 13 of 94 individuals (14%) in the control group. Five-year results have been published for the TAG 99-01 study (Makaroun, 2008). At 5 years, aneurysm related mortality was lower for the TAG individuals compared to those who underwent open repair.

The Zenith®‡ TX2®‡ Thoracic TAA Endovascular Graft with the H&LB One-Shot™‡ Introduction System (Cook Medical, Inc., Bloomington, IN) received U.S. Food and Drug Administration (FDA) clearance through the Premarket Approval (PMA) process on May 21, 2008, subject to submission of post-approval reports consistent with established FDA Medical Device Reporting Regulations. This device is indicated for the endovascular treatment of individuals with aneurysm or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair, including:

- Adequate iliac/femoral access compatible with the required introduction systems, and
- Non-aneurysmal aortic segments (fixation sites) proximal and distal to the aneurysm or ulcer with a length of at least 25 mm and a diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm (FDA, 2008).

Additional devices include the Valiant®‡Thoracic Stent Graft with the Captivia Delivery System (Medtronic Vascular, Inc., Santa Rosa, CA), which obtained FDA clearance for expanded indications for the EVAR of isolated lesions (excluding dissections) of the descending thoracic aorta in individuals meeting specific anatomic specifications (FDA, 2012). The Talent™‡ Thoracic Stent Graft System (also from Medtronic Vascular, Inc., Santa Rosa, CA) had obtained FDA clearance on June 5, 2008 for repair of the descending thoracic aorta with specific anatomical labeling specifications (FDA, 2008).

In 2010, guideline recommendations for Diagnosis and Management of Individuals with Thoracic Aortic Disease were published in a report from 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 (Hiratzka, 2010). This report gives a Class I recommendation for EVAR stent grafting of degenerative or traumatic aneurysms of the descending thoracic aorta for aneurysms exceeding 5.5 cm, saccular aneurysms, or postoperative pseudoaneurysms where, "Endovascular stent grafting should be strongly considered when feasible." This information is consistent with the criteria in this document for aneurysms of the descending thoracic aorta. Beyond this recommendation, the report discusses other indications for EVAR, (for example, aneurysms of the ascending aorta and aortic arch, acute and chronic ascending aortic ruptures) with cautionary comments and does not provide a recommendation for or against EVAR procedures. The report notes that:

> To date, no stent graft devices have been approved by the FDA for repair of aneurysms or other conditions of the ascending aorta or of the aortic arch and the long-term durability of endovascular stent grafting is not known in these additional patient populations.

A scientific statement on The Surgical Management of Descending Thoracic Aortic Disease: open and endovascular approaches was issued in 2010 from the American Heart Association which noted the following:

> Treatment of acute aortic syndromes that affect the descending thoracic aorta continues to evolve with the development of new technologies and management strategies. Although data presented in this summary have highlighted current outcomes of endovascular stenting compared with conventional open repair, it must be stressed that there have been no prospective randomized trials to compare these treatment strategies on a head-to-head basis. In addition, although endovascular stenting offers a minimally invasive method of treatment, its long-term durability is still largely unknown. Ongoing experience and national and international registries will continue to define precise roles for both surgical and endovascular therapy (Coady, 2010).

The published evidence addressing EVAR procedures for acute conditions of the descending thoracic aorta is limited, including dissections of the descending thoracic aorta and repair of traumatic descending aortic injury. In 2010, Nienaber published 1-year outcomes data from the Investigation of Stent grafts in patients with Type B Aortic Dissection (INSTEAD) trial which was a prospective trial of 140 subjects with stable type B dissection that compared elective stent graft placement, in addition to optimal medical therapy (n=72) to optimal medical therapy with surveillance (n=68). The primary endpoint was the 1-year all-cause mortality rate which showed no significant difference in outcomes for both groups at 1 year. Cumulative survival was 97.0% ± 3.4% for the optimal medical therapy group vs. 91.3% ± 2.1% in the TEVAR group (p=0.16). Additional secondary endpoints were also similar in the two treatment groups (aorta-related mortality, p=0.42; risk for the combined endpoint of aorta-related death from rupture and progression to need for conversion or additional interventional procedures, p=0.86). Continued aortic remodeling was suggested in both treatment groups by 91.3% in the TEVAR group and 19.4% in the medical treatment group (p<0.001). The authors concluded that elective stent graft placement does not improve the 1-year survival rate and adverse events in survivors of uncomplicated type B aortic dissection, despite favorable aortic remodeling (Nienaber, 2010; additional citation relevant to aortic remodeling: Conrad, 2009b).

A multidisciplinary subcommittee of the Society for Vascular Surgery Outcomes Committee published a report in 2011 on the results of TEVAR for acute, complicated, type B aortic dissection

(cTBAoD). This report describes analysis of 1-year outcomes after TEVAR in 99 subjects with descending thoracic aortic dissection, 85 of whom had cTBAoD with either rupture or malperfusion and symptom onset of 14 days or less (that is, considered acute). An additional 11 subjects were considered subacute (15 to 30 days since onset), and 3 more were considered chronic (31 to 90 days since onset) until they required intervention. This report focused on the acute cohort. Clinical data were systematically collected from five physician-sponsored investigational device exemption (IDE) clinical trials between 2000 and 2008. Adverse events were reported early (30 days or less) and late (> 30 days). Major adverse events included death, stroke, myocardial infarction, renal failure, respiratory failure, paralysis, and bowel ischemia. Among the acute subjects, 31.8% had rupture and 71.8% had malperfusion, including 55.7% lower extremity, 36.1% renal, 19.7% visceral, 8.2% other, and 3.3% spinal cord (some subjects had more than one source). Early major adverse events occurred in 37.6% of acute subjects, including death (10.6%), stroke (9.4%), renal failure (9.4%), and paralysis (9.4%); late adverse events included vascular (15.8%), cardiac (10.5%), gastrointestinal (6.6%), and hemorrhage (5.3%). The point-estimate mortality rate was 10.8 (95% CI, 4.1-17.5) at 30 days and 29.4 (95% CI, 18.4-40.4) at 1 year, when 34 subjects remained at risk. The authors concluded that emergency TEVAR for individuals with cTBAoD (malperfusion or rupture) provides acceptable mortality and morbidity results out to 1 year (White, 2011).

A systematic review and meta-analysis was also published in 2010 which reviewed the available observational (nonrandomized) evidence regarding early and late outcomes for TEVAR in acute cTBAoD , which was confined to dissection of the descending aorta presenting within 14 days from the onset of symptoms. A total of 76 articles were reviewed including 2 papers with data from the International Registry of Acute Aortic Dissection (IRAD). This review included 1951 subjects meeting the inclusion criteria who underwent TEVAR between 1999 and 2010 in Europe and North America. The cumulative all-cause 30-day mortality (or in-hospital mortality) was significantly reduced for TEVAR (pooled event rate of 11.5%) compared to open repair (40%). Early major complications of TEVAR included stroke (6.3%), paraplegia (4.9%), retrograde Type A aortic dissection (7%), renal impairment including dialysis (6.9%), bowel infarction (4.1%), and vascular problems including amputation (2.5%). The mean follow-up time was 24.2 months. Late mortality for the TEVAR subjects was calculated to be 8.2% with occurrence of late aortic rupture calculated at 3.2%, development of false lumen thrombosis 76.1%, and reintervention rates reported separately as endovascular intervention was required in 11.3% and surgical intervention was required in 7.7% of cases. The authors of this meta-analysis concluded that TEVAR may reduce early mortality,

paraplegia and vascular complications, as compared to open surgical repair, in individuals with acute cTBAoD . However, no significant difference between TEVAR and open surgical repair was seen in late mortality, reintervention rates, renal dysfunction (including dialysis), and stroke rates. Acknowledged limitations of this systematic review included the lack of randomized comparative trials, the short-term duration of outcomes data and the small sample size of the majority of included studies, which can potentially affect the reliability of results analysis (Luebke, 2010).

Another systematic review and meta-analysis was published in 2010 which evaluated the outcomes of open repair (n=81) vs. EVAR (n=143) of ruptured TAA. The 30-day mortality was 19% for subjects treated with EVAR, compared to 33% for those treated with open repair (p=0.016). The 30-day incidence of myocardial infarction (MI) was 3.5% for those treated with EVAR vs. 11.1% treated with open repair ($p<0.05$). Rates of stroke and paraplegia were also increased in the surgically treated group, but did not reach statistical significance. Additional vascular interventions were performed in 9.1% of EVAR subjects vs. 2.3% of surgically treated subjects (p=0.169). Regarding safety, during a median follow-up of 17 ± 10 months, 5 additional subjects in the EVAR group died of aneurysm-related causes; endoleak was reported in 11.1%; and endograft migration was reported in 1 subject. The authors noted that the durability and development of EVAR related complications remain concerns and that further surveillance of endografts is required. Limitations to the data interpretation were also noted due to unavailable follow-up data for the open surgical group, and the authors commented that further improvements in EVAR techniques and stent graft design is necessary (Jonker, 2010).

The evidence, to date, regarding the outcomes of TEVAR for thoracic aortic injury or transection is limited to small case series and observational studies conducted primarily at single institutions which have demonstrated the utility of TEVAR in this setting (Dake, 2011; Dumfarth, 2011; Patel, 2011). In 2008, results were reported and compared between two prospective multi-center studies, the American Association for the Surgery of Trauma (AAST1 and AAST2). The AAST1 study was completed in 1997 and included 274 subjects from 50 participating centers over a period of 30 months. The AAST2 study was completed in 2007 and included 193 subjects from 18 centers over a period of 26 months. The comparisons between the two studies included the method of definitive diagnosis of the aortic injury (computed tomography [CT] scan, aortography, transesophageal echocardiogram [TEE] or magnetic resonance imaging), the method of definitive aortic repair (open repair vs. EVAR, clamp and sew vs. bypass techniques), the time from injury to procedure (early vs.

delayed repair), and outcomes (survival, procedure-related paraplegia, other complications). Notably, in the AAST1 study, all subjects were treated by open repair whereas in the AAST2 only 35.2% were treated by open repair, and the remaining 64.8% were treated with EVAR grafts. This brief summary will focus on the comparison of operative outcomes between the two studies. Overall early mortality was 22% in the AAST1 study and 13% in the AAST2 (p=0.02). The paraplegia rate following open repair dropped from 8.7% in AAST1 to 2.9% in AAST2; the paraplegia rate for TEVAR in the AAST2 was 0.8%. The early procedure-related complication rates were similar in both studies for the open repairs (0.5% AAST1 vs. 1.5% AAST2) but 13.5% in AAST2 for EVAR. These device-related endovascular early complications included 18 endoleaks, 4 access vessel injuries, 4 subclavian artery occlusions, 1 carotid occlusion, 2 strokes, 1 paraplegia, 1 partial collapse of the stent/graft and 1 insertion site infection. The authors commented that the higher early complication rates seen for EVAR in the AAST2 may be due, in part, to stent graft technology and practitioner experience with enrollment that dated back to 2005, which may have contributed to an overestimation of early complication rates that would not be representative of outcomes with EVAR repair of traumatic aortic injuries in trauma centers today (Demetriades, 2008).

In 2011, the Society for Vascular Surgery®‡ (SVS) pursued development of clinical practice guidelines for the management of traumatic thoracic aortic injuries with TEVAR. The Society selected a panel of experts and conducted a systematic review and meta-analysis of the literature (Murad, 2011). They used the Grading of Recommendations Assessment, Development and Evaluation methods (GRADE) to develop and present their recommendations. The systematic review included 7768 subjects from 139 studies. According to this document:

> The mortality rate was significantly lower in patients who underwent endovascular repair, followed by open repair, and nonoperative management (9%, 19%, and 46%, respectively; P <.01). Based on the overall very low quality of evidence, the committee suggests that endovascular repair of thoracic aortic transection is associated with better survival and decreased risk of spinal cord ischemia, renal injury, graft and systemic infections compared with open repair or nonoperative management (Grade 2, Level C). However, this finding should be tempered by the current lack of suitable devices that can accommodate the unique anatomy of these patients, which has occasionally resulted in severe procedure-related complications and the unknown natural history of the endovascular repair and the optimal follow-up strategy. The committee was also surveyed on a variety of issues that were not specifically addressed by the

meta-analysis. On these select matters, the majority opinions of the committee suggest urgent repair following stabilization of other injuries, observation of minimal aortic defects, selective (vs. routine) revascularization in cases of left subclavian artery coverage, and that spinal drainage is not routinely required in these cases.

The specific guideline recommendation is as follows: "The committee suggests that endovascular repair of traumatic thoracic aortic injuries be performed preferentially over open surgical repair or nonoperative management. This recommendation is based on very low quality evidence (Grade 2, Level C)" (Lee, 2011).

Note: The grading system utilized by the SVS in making the above recommendations is as follows:

Grade of Recommendation:
1 – Strong;
2 – Weak.

Quality of Evidence:
A – High;
B – Moderate;
C – Low or very low.

In conclusion, the published literature regarding EVAR treatment of descending thoracic aortic dissection and traumatic thoracic aortic disruption (transection) is limited to observational data with comparison of outcomes to historical controls. Despite these limitations, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas agree that these techniques may be suitable in selected individuals, particularly those with cTBAoD of the descending thoracic aorta with end-organ compromise and traumatic thoracic aortic transections, who are at risk of immediate mortality and for whom EVAR treatment offers a reasonable chance of meaningful survival (Thrumurphy, 2011; Zhang, 2012). Use of fenestrated and branched endovascular/endoluminal stent graft devices is considered to be in accordance with generally accepted standards of medical practice for repair of juxtarenal and thoraco-abdominal aortic aneurysms when the individual is not a candidate for open surgical repair due to medical comorbidities.

Supplemental Information/Definitions

Abdominal Aorta: The portion of the aorta extending from the diaphragm to the iliac arteries in the groin.

Aneurysm: A dilating, bulging or ballooning out of a part of the wall of a blood vessel where the wall has weakened, often due to the build-up of plaque.

Aortic Dissection (AoD): A disruption of the media layer of the aorta with bleeding within and along the wall of the aorta resulting in separation of the layers of the aorta. The Stanford classification system divides dissections into 2 categories, those that involve the ascending aorta and those that do not as follows:

- Type A: All dissections involving the ascending aorta regardless of the site of origin (surgery
- usually recommended);
- Type B: All dissections that do not involve the ascending aorta (nonsurgical treatment usually recommended).

Note: Involvement of the aortic arch without involvement of the ascending aorta in the Stanford classification is labeled as Type B (Hiratzka, 2010).

Complicated Type B dissection: This term refers to dissections that originate in the descending thoracic aorta where the effects of major circulatory compromise complicate the clinical prognosis, such as impending rupture, rapid dilatation, and malperfusion to vital organs, such as the kidneys and spinal cord. The acute phase is defined as the first 2 weeks following onset of symptoms.

For the purposes of this document, Type B aortic dissection is limited to dissections of the descending thoracic aorta and not the aortic arch.

Aortoiliac: Pertaining to both the aorta and the iliac arteries.

Ehlers Danlos syndrome: A group of genetic conditions that have resulted from defects in a collagen molecule, which would normally give strength and adhesion to the body's tissues.

Endovascular or Endoluminal stent graft: A piece of graft material (fabric tubing), within which metal stents (a framework) have been placed to support and secure the device to the wall of the aorta.

Iliac arteries: Refers to three vascular structures located in the pelvis as follows:
Common iliac artery - forms at the terminus (distal end) of the aorta;
External iliac artery - forms when the common iliac artery bifurcates (splits) and continues as the femoral artery at the inguinal ligament;
Internal iliac artery - forms when the common iliac artery bifurcates and supplies the perineum and sexual organs with oxygenated blood.

Marfans syndrome: A genetic disorder of the connective tissues. If the largest artery (the aorta) is affected, the diameter will likely widen or dilate.

Perioperative mortality: Death from any cause within 30 days of a procedure.

Thoracic aorta: The portion of the aorta extending from the heart to the level of the diaphragm.

Thoracoabdominal aortic aneurysm (TAAA): Type I involves most of the descending thoracic aorta from the origin of the left subclavian to the suprarenal abdominal aorta. Type II is the most extensive, extending from the subclavian to the aortoiliac bifurcation. Type III involves the distal thoracic aorta to the aortoiliac bifurcation. Type IV TAAAs are limited to the abdominal aorta below the diaphragm. Type V, which extends from the distal thoracic aorta including the celiac and superior mesenteric origins but not the renal arteries.

Transection: This term refers to traumatic aortic rupture, which is also called traumatic aortic disruption or transection. This is a condition where the aorta is torn or ruptured as the result of trauma. The condition is frequently fatal due to the profuse bleeding that results from the rupture.

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Policy History

Original Effective Date: 01/27/2003
Current Effective Date: 09/11/2023

11/21/2002	Medical Policy Committee review
01/27/2003	Managed Care Advisory Council approval
01/20/2004	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged
01/31/2005	Managed Care Advisory Council approval
05/17/2005	Medical Policy Committee review. Format revision. Policy statement changed from endoprostheses (i.e., endovascular grafts) as a treatment of abdominal aortic aneurysms (infrarenal abdominal or aortoiliac aneurysms) to: the use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms. Patient selection criteria expanded to include; "The use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms may be considered medically necessary as a treatment of abdominal aortic aneurysms in any of the following clinical situations, consistent with the FDA-labeled indications for the AneurRx device." Investigational statement added to address non FDA-Approved devices and situations when patient selection criteria are not met.
05/23/2005	Managed Care Advisory Council approval

07/07/2006	Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/02/2006	Medical Director Review
08/09/2006	Medical Policy Committee approval. Rationale /Source and rationale updated.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Policy statement added for treatment of ruptured abdominal aortic aneurysm as investigational.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Changed coverage statement from investigational to eligible for coverage with criteria for ruptured abdominal aortic aneurysms.
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. For clarification, added that the use of endoprostheses approved by the U.S. FDA as a treatment of abdominal aortic aneurysms is considered investigational for certain clinical situations.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. No change to coverage.
03/04/2013	Coding revised
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review

06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Added "stent" to the title. Coverage eligibility unchanged.
01/01/2018	Coding update
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/31/2020	Coding update
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Revised the eligible for coverage section for clarity. Coverage eligibility unchanged.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Title changed from "Endovascular Stent Grafts for Abdominal Aortic Aneurysms" to "Endovascular/Endoluminal Repair of Aortic Aneurysms, Aortoiliac Disease, Aortic Dissection and Aortic Transection". Extensive policy revisions.

Next Scheduled Review Date: 08/2024

Coding

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Endovascular/Endoluminal Repair of Aortic Aneurysms, Aortoiliac Disease, Aortic Dissection and Aortic Transection

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 09/11/2023

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

Code Type	Code
CPT	34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34715, 34716, 34717, 34808, 34812, 34813, 34820, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848 Add codes effective 09/01/2023: 33880, 33881, 33883, 33884, 33886, 75956, 75957, 75958, 75989 Delete codes effective 09/01/2023: 34714, 34718, 34833
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

*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 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.

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

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