



Louisiana

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

Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

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:

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- 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.

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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 Marfan's or Ehlers Danlos Syndromes. Both TAA and AAA can be surgically repaired using stents and grafts. 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

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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 participants 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 participants treated with the Zenith Fenestrated AAA Endovascular Graft and in matched participants 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 participants 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 group. One Zenith fenestrated recipient experienced a major adverse event

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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 participant 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 participants 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 participants 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 participant 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 participants 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 participants that underwent reintervention for renal stenosis. The investigators concluded that the outcomes were reasonable for the participants 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 participants 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,

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nonrandomized multi-center study was designed to evaluate the Zenith Fenestrated AAA Endovascular Graft for juxtarenal AAAs. Sixty-seven participants (54 individuals, mean age 74 ± 8 years) were prospectively enrolled at 14 U.S. centers from 2005 to 2012. Fenestrated stent grafts were used in participants 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 $88.8 \pm 4.2\%$ and freedom from aneurysm-related mortality was $96.8 \pm 2.3\%$. 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 $82.7 \pm 4.1\%$ and $95.7 \pm 2.1\%$ at 5 years, respectively. Dialysis was required in 1 participant 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 participants had sac shrinkage at 5 years. Of the 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 $63.5 \pm 7.2\%$ 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 participants, death in 7 participants, and withdrawal or loss to follow-up in 12 participants.

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

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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 participants and eight chimney endovascular aneurysm repair (CH-EVAR) cohorts with 158 JAA participants 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 participants from 37 UK hospitals between Sept 1, 1999, and Aug 31, 2004. Participants 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, participants 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

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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).

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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:

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- 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).

Kwolek and colleagues (2023) published the Looking at EVAR Outcomes by Primary Analysis of Randomized Data (LEOPARD) trial. This prospective, randomized, multi-center trial, which compared the anatomically fixated system (AFX2 Endlogix, [Endologix LLC. Irvine, CA]) to endografts with proximal fixation (PF [Cook Medical Zenith Flex; Gore Excluder; and Medtronic Endurant II]) in individuals with infrarenal abdominal aortic aneurysms. The participants were treated with AF devices (n=235) and with PF devices (n=220), the outcome measured was the absence of aneurysm-related complications. This was a composite outcome consisting of perioperative death defined as death within 30 days of the procedure, aneurysm rupture, conversion to open surgical repair, postoperative endoleaks, endograft migration (10 mm), aneurysm enlargement (5 mm), endograft limb occlusion, and device-or aneurysm-related reintervention. The results demonstrated no difference in aneurysm-related mortality, all-cause mortality, rupture, secondary interventions, and type I and type III endoleak between the 2 groups. The type III endoleak rate at 5 years for the AFX group was 1.5% and 0.0% for the comparator group (p=0.11). There was a lower type II endoleak rate in the AF group at 5 years, 78.8% compared to 68.4% in the PF group (p=0.037). There were no open surgical conversions (0.0%) in the AF group and 4 (2.0%) in the PF group. The authors concluded that the study demonstrated there was no clinically significant difference in overall aneurysm-related outcomes between participants randomized to the AFX endograft system or commercially available endografts with PF. It is noted this study was funded by Endologix.

Wang and colleagues (2023) published a Cochrane review that evaluated the benefits and risks of a percutaneous access technique compared to cut-down femoral artery access technique in individuals undergoing elective bifurcated abdominal EVAR. Three studies were examined with 318 participants; 189 underwent percutaneous technique and 129 were treated by cut-down femoral

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artery access. One study had a small sample size and did not adequately report the method of randomization, allocation concealment or preselected outcomes. The other 2 larger studies had low risk of bias and good methodology; although 1 study had a high risk of bias in selective reporting. The review demonstrated no clear difference in short-term mortality between groups, with only 1 death occurring overall, in the percutaneous group (95% confidence, 2 studies, 181 participants; interval low-certainty evidence). There was 1 failure of aneurysm exclusion in the surgical cut-down femoral artery access group (95% CI; 1 study, 151 participants; moderate-certainty evidence). For wound infection, there was no clear difference between groups (95% CI; 3 studies, 318 participants; moderate-certainty evidence). The differences in operating time, with the percutaneous approach being faster than cut-down femoral artery access (mean difference -21.13 minutes, 95% CI, 3 studies, 318 participants; low-certainty evidence). The authors concluded:

Skin puncture may make little to no difference to short-term mortality. There is probably little or no difference in failure to seal the aneurysms, wound infection, major complications within 30 days or while in hospital, medium- to long-term (6 months) complications and bleeding complications between the 2 groups. Compared with exposing the femoral artery, skin puncture may reduce the operating time slightly. We downgraded the certainty of the evidence to moderate and low as a result of imprecision due to the small number of participants, low event rates and wide CIs, and inconsistency due to clinical heterogeneity. As the number of included studies was limited, further research into this technique would be beneficial.

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

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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

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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.

In 2022 The American College of Cardiology with the American Heart Association published a joint Guideline for the Diagnosis and Management of Aortic Disease. The recommendations regarding Endovascular Versus Open Repair of Descending TAA (level of evidence B-NR [data derived from one or more non-randomized trials or meta-analysis]) include the following:

- 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.
- In patients with a descending TAA that meets criteria for repair with TEVAR, who have smaller or diseased access vessels, considerations for alternative vascular access are recommended.
- In patients with a descending TAA that meets criteria for intervention, who have anatomy unsuitable for endovascular repair, and who are without significant comorbidities and have a life expectancy of at least 10 years, open surgical repair is reasonable.

The committee concluded that although no RCTs comparing TEVAR with open repair of descending TAA exist, the pivotal device trials showed decreased perioperative morbidity, increased clinical utility, and reduced follow-up aneurysm-related mortality compared with open surgical repair. However, there was need for reintervention after TEVAR. Although the trials demonstrated improved outcomes with TEVAR, Medicare claims data demonstrated that the perioperative advantage was lost within the first year after intact aneurysm repair, with a 5-year

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survival that was worse after TEVAR compared to open repair, at 79% versus 89%, respectively $p < 0.0001$). Additional studies examining etiology of the declining benefit from endovascular repair over time are needed. For individuals with connective tissue disorders, heritable thoracic aortic disease, or a longer life expectancy, open surgical technique is reasonable. Open surgical technique for descending TAA reflected a volume-outcomes relationship: Large institutions demonstrated positive outcomes with open repair that are not reproducible at lower volume institutions. Clinical decisions regarding whether to proceed with TEVAR versus open repair must balance factors including the appropriate anatomy and access, with the higher need for reintervention with TEVAR compared to the elevated perioperative risk associated with open surgical repair (Isselbacher, 2019).

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 individuals with Type B Aortic Dissection (INSTEAD) trial which was a prospective trial of 140 participants 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 $97.0\% \pm 3.4\%$ for the optimal medical therapy group vs. $91.3\% \pm 2.1\%$ in the TEVAR group ($p=0.16$). Additional

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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 participants 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 participants 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 participants, 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 participants had more than one source). Early major adverse events occurred in 37.6% of acute participants, 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 participants 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 were 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

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International Registry of Acute Aortic Dissection (IRAD). This review included 1951 participants 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 participants 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 were 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 participants 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).

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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 participants 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 participants 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

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Evaluation methods (GRADE) to develop and present their recommendations. The systematic review included 7768 participants 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.

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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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology and American Heart Association

In 2022, the American College of Cardiology and the American Heart Association (ACC/AHA) published a guideline for the management of aortic disease, including abdominal aortic aneurysm (AAA). Recommendations from the guideline regarding AAA repair are listed in Table 1.

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Table 1. Guideline on Management of Patients with Aortic Disease: Abdominal Aortic Aneurysm Repair

Recommendation	COR	LOE
In patients with nonruptured AAA with low to moderate operative risk and suitable anatomy, a shared decision-making process weighing the risks and benefits of endovascular versus open repair is recommended.	I	A
In patients with nonruptured AAA with high operative risk, endovascular repair is reasonable to reduce risk of 30-day morbidity, mortality, or both.	IIa	B-NR
In patients with nonruptured AAA with moderate to high operative risk and suitable anatomy for an FDA-approved fenestrated endovascular device, endovascular repair is reasonable over open repair to reduce risk of perioperative complications.	IIa	B-NR
In patients with ruptured AAA with suitable anatomy, endovascular repair is recommended over open repair to reduce risk of morbidity and mortality.	I	B-R

AAA: abdominal aortic aneurysm; COR: class of recommendation; FDA: Food and Drug Administration; LOE: level of evidence; NR: nonrandomized; R: randomized.

In 2011, the ACC/AHA released an update to their 2005 guidelines on the management of AAAs that focused on the management of patients with peripheral artery disease. These guidelines made the following recommendations (Table 2).

Table 2. Guidelines on Management of Patients With Peripheral Artery Disease

Recommendation	COR	LOE
Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good surgical candidates	I	A
Periodic long-term surveillance imaging should be performed to monitor for endoleak, confirm graft position, document shrinkage or stability of the excluded aneurysm sac, and determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms	I	A

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Open aneurysm repair is reasonable to perform in patients who are good surgical candidates but who cannot comply with the periodic long-term surveillance required after endovascular repair	IIa	C
Endovascular repair of infrarenal aortic aneurysms in patients who are at high surgical or anesthetic risk as determined by the presence of coexisting severe cardiac, pulmonary, and/or renal disease is of uncertain effectiveness	IIb	C

AAA: abdominal aortic aneurysm; COR: class of recommendation; LOE: level of evidence.

In 2006, the ACC/AHA suggested in their professional guidelines, based on both randomized and nonrandomized trials, that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open surgeries.

Society of Interventional Radiology

In 2010, the Society of Interventional Radiology developed guidelines on the use of endovascular aneurysm repair (EVAR) that were endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association. These guidelines indicated that:

“Indications for EVAR are currently the same as open repair....”

“Patient preference for EVAR versus open repair should be considered when appropriate....”

“Endovascular abdominal aortic aneurysm repair should be considered as having an intermediate to high cardiac risk that ranges from 3% to 7%.”

There has been increasing use of EVAR for ruptured aneurysms. “Achieving optimal EVAR results for ruptured AAA requires establishment of a treatment protocol involving the emergency department, the endovascular team, anesthesiology, and the operating room personnel.”

“Lifelong imaging surveillance of patients after EVAR is critical for (i) the detection and, if possible, the characterization of endoleaks; (ii) evidence of expansion or shrinkage of the residual AAA sac through measurement of aneurysm size, volume calculation, and identification

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of substantial changes in aneurysm dimensions; (iii) detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture; and (iv) evaluation of the long-term performance of the endoprosthesis.”

Society for Vascular Surgery

In 2018, the Society for Vascular Surgery published guidelines for the treatment of AAAs. As in previous publications, these guidelines indicated that open surgery and EVAR are options for patients with aneurysms that meet the current treatment threshold. These guidelines also made the following recommendations (Table 3).

Table 3. Guidelines on Management of Patients With Aneurysms

Recommendation	QOE	LOR
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	Moderate	Strong
EVAR may be considered for high-risk patients unfit for surgical repair	Low	Weak
For patients with ruptured aneurysm, immediate repair is recommended	High	Strong

AAA: abdominal aortic aneurysm; EVAR: endovascular aneurysm repair; LOR: level of recommendation; QOE: quality of evidence.

U.S. Preventive Services Task Force Recommendations

Recommendations from the U.S. Preventive Services Task Force (USPSTF) on AAA screening were updated on December 10, 2019. The USPSTF notes the following in their section on "Current Practice" as it relates to this topic:

"The standard of care for elective repair is that patients with an AAA of 5.5 cm or larger in diameter should be referred for surgical intervention with either open repair or EVAR. This recommendation is based on RCTs conducted in men. The AAA size needed for surgical intervention in women may differ. As a result, guidelines from the Society for Vascular Surgery recommend repairing AAAs

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between 5.0 and 5.4 cm in diameter in women. However, concerns about poorer surgical outcomes in women, who have more complex anatomy and smaller blood vessels, have led some to caution against lowering the threshold for surgical intervention in women."

National Institute for Health and Care Excellence

Recommendations for the diagnosis and management of AAAs were published by the National Institute for Health and Care Excellence (NICE) in March 2020. Recommendations for repairing unruptured aneurysms include:

- "1.5.1: Consider aneurysm repair for people with an unruptured abdominal aortic aneurysm (AAA), if it is:
 - symptomatic
 - asymptomatic, larger than 4.0 cm, and has grown by more than 1 cm in 1 year (measured inner-to-inner maximum anterior-posterior aortic diameter on ultrasound)
 - asymptomatic and 5.5 cm or larger (measured inner-to-inner maximum anterior-posterior aortic diameter on ultrasound)."
- "1.5.4: Consider endovascular aneurysm repair (EVAR) for people with unruptured AAAs who meet the criteria in recommendation 1.5.1 and who have abdominal comorbidity, such as a hostile abdomen, horseshoe kidney or a stoma, or other considerations, specific to and discussed with the person, that may make EVAR the preferred option"
- "1.5.5: Consider EVAR or conservative management for people with unruptured AAAs meeting the criteria in recommendation 1.5.1 who have anaesthetic risks and/or medical comorbidities that would contraindicate open surgical repair."

Recommendations for repairing ruptured aneurysms include:

- "1.6.1: Consider endovascular aneurysm repair (EVAR) or open surgical repair for people with a ruptured infrarenal abdominal aortic aneurysm (AAA). Be aware that:
 - EVAR provides more benefit than open surgical repair for most people, especially men over 70 and women of any age
 - Open surgical repair is likely to provide a better balance of benefits and harms in men under 70."
- "1.6.2: Consider open surgical repair for people with a ruptured AAA if standard EVAR is unsuitable."

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Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01937949 ^a	Clinical Outcomes and Quality of Life Measures in Patients Treated for Complex Abdominal Aortic Aneurysms With Fenestrated Stent Grafts	200	May 2030
NCT02996396 ^a	Multicenter, Observational, Registry to Assess Outcomes of Patients Treated With the CE Nellix ^{®‡} System for Endovascular Abdominal Aortic Aneurysm Repair	300	Nov 2024
NCT03298477 ^a	Prospective, Multicenter, Single Arm Safety and Effectiveness Confirmatory Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix System IDE Study (EVAS 2 Confirmatory IDE Study)	98	Aug 2025
NCT02489539 ^a	Assessment of the GORE ^{®‡} EXCLUDER ^{®‡} Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms	175	Dec 2027
NCT03180996 ^a	A Prospective, Global, Multicentre, Real World Outcome Study of Fenestrated Endovascular	160	Dec 2030

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	Aneurysm Repair Using the Fenestrated Anaconda ^{TM†} Device		
NCT03446287	Clinical Outcomes and Quality of Life Measures in Patients Treated With Open Surgical Repair for Complex Aortic Aneurysms	150	Dec 2026
<i>Unpublished</i>			
NCT02485496 ^a	SECURE - A poSt-market Registry in Patients With infraEnal aortiC Aneurysm Undergoing endovasculaR Stenting With the New E-tegra Stent Graft System	100	Dec 2021
NCT04220177 ^a	Prospective, Open-label, Multicenter, Non-randomized Clinical Study to Determine the Safety and Efficacy of SETA LATECBA Stent Graft for Endovascular Repair Therapy (EVAR) in Subjects With Abdominal Aortic Aneurysm (AAA)	42	Mar 2022
NCT01726257 ^a	Prospective, Multicenter, Single Arm Safety and Effectiveness Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix ^{®‡} System: A Pivotal and Continued Access Study	333	Dec 2022
NCT03966521	The British Society of Endovascular Therapy Conformable EndoVascular Repair (BSET-CLEVAR) Registry	105	Dec 2022

NCT: national clinical trial.

^a Denotes an industry-sponsored or cosponsored trial.

Definitions:

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

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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:

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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.

References

Peer Reviewed Publications:

1. Amiot S, Haulon S, Becquemin JP, et al. Fenestrated endovascular grafting: the French multicenter experience. *Eur J Vasc Endovasc Surg.* 2010; 39(5):537-544.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

2. Arya N, Makar RR, Lau LL, et al. An intention-to-treat by endovascular repair policy may reduce overall mortality in ruptured abdominal aortic aneurysm. *J Vasc Surg.* 2006; 44(3):467-471.
3. Bavaria JE, Apoo JJ, Makaroun MS, et al. Endovascular stent grafting versus open surgical repair of descending thoracic aortic aneurysms in low risk patients. A multicenter comparative trial. *J Thorac Cardiovasc Surg.* 2007; 133(3):285-288.
4. Bavaria JE, Brinkman WT, Hughes GC, et al. Five-year outcomes of endovascular repair of complicated acute type B aortic dissections. *J Thorac Cardiovasc Surg.* 2022; 163(2):539-548.e2.
5. Becquemin JP, Pillet JC, Lescalie F, et al. A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients. *J Vasc Surg.* 2011; 53(5):1167-1173.
6. Biancari F, Catania A, D'Andrea V. Elective endovascular vs. open repair for abdominal aortic aneurysm in patients aged 80 years and older: systematic review and meta-analysis. *Eur J Vasc Endovasc Surg.* 2011; 42(5):571-576.
7. Blankensteijn JD, de Jong SECA, Prinssen M, et al.; Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial Group. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. *N Engl J Med.* 2005; 352(23):2398-2405.
8. Blankensteijn LL, Dijkstra ML, Tielliu IF, et al. Midterm results of the fenestrated Anaconda endograft for short-neck infrarenal and juxtarenal abdominal aortic aneurysm repair. *J Vasc Surg.* 2017; 65(2):303-310.
9. Brewster DC, Jones JE, Chung TK, et al. Long-term outcomes after endovascular abdominal aortic aneurysm repair: the first decade. *Ann Surg.* 2006; 244(3):426-438.
10. Brown LC, Thompson SG, Greenhalgh RM, et al. Incidence of cardiovascular events and death after open or endovascular repair of abdominal aortic aneurysm in the randomized EVAR trial 1. *Br J Surg.* 2011; 98(7):935-942.
11. Brunkwall J, Kasprzak P, Verhoeven E, et al. Endovascular repair of acute uncomplicated aortic type B dissection promotes aortic remodeling: 1 year results of the ADSORB trial. *Eur J Vasc Endovasc Surg.* 2014; 48(3):285-291.
12. Brunkwall J, Lammer J, Verhoeven E, et al. ADSORB: a study on the efficacy of endovascular grafting in uncomplicated acute dissection of the descending aorta. *Eur J Vasc Endovasc Surg.* 2012; 44(1):31-36.
13. Cambria RP, Crawford RS, Cho JS, et al. A multicenter clinical trial of endovascular stent graft repair of acute catastrophes of the descending thoracic aorta. *J Vasc Surg.* 2009; 50(6):1255-1264.e1-4.

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Policy # 00035

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14. Canaud L, Alric P, Branchereau P, et al. Open versus endovascular repair for patients with acute traumatic rupture of the thoracic aorta. *J Thor Cardiovasc Surg.* 2011; 142(5):1032-1037.
15. Cao P, De Rango P, Verzini F, et al. Comparison of surveillance versus aortic endografting for small aneurysm repair (CAESAR): results from a randomized trial. *Eur J Vasc Endovasc Surg.* 2011; 41(1):13-25.
16. Carpenter JP. The Powerlink bifurcated system for endovascular aortic aneurysm repair: four-year results of the U.S. multicenter trial. *J Cardiovasc Surg (Torino).* 2006; 47(3):239-243.
17. Chambers D, Epstein D, Walker S, et al. Endovascular stents for abdominal aortic aneurysms: a systematic review and economic model. *Health Technol Assess.* 2009; 13(48):1-189, 215-318, iii.
18. Chemelli-Steingruber I, Chemelli A, Strasak A, et al. Endovascular repair or medical treatment of acute type B aortic dissection? A comparison. *Eur J Radiol.* 2010; 73(1):175-180.
19. Chen L, Qi RD, Liu W, et al. Repair of complicated chronic type b dissection with distal aortic arch involvement using left subclavian artery transposition with implantation of a stented elephant trunk. *Thorac Cardiovasc Surg.* 2017; 65(2):99-104.
20. Chisci E, Kristmundsson T, de Donato G, et al. The AAA with a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. *J Endovasc Ther.* 2009; 16(2):137-146.
21. Conrad MF, Adams AB, Guest JM, et al. Secondary intervention after endovascular abdominal aortic aneurysm repair. *Ann Surg.* 2009a; 250(3):383-389.
22. Conrad MF, Crawford RS, Kwolek CJ, et al. Aortic remodeling after endovascular repair of acute complicated type B aortic dissection. *J Vasc Surg.* 2009b; 50(3):510-517.
23. Davis FM, Albright J, Battaglia M, et al. Fenestrated repair improves perioperative outcomes but lacks a hospital volume association for complex abdominal aortic aneurysms. *J Vasc Surg.* 2021; 73(2):417-425.
24. De Bruin JL, Baas AF, Buth J, et al.; DREAM Study Group. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. *N Engl J Med.* 2010; 362(20):1881-1889.
25. D'Elia P, Tyrrell M, Sobocinski J, et al. Endovascular thoracoabdominal aortic aneurysm repair: a literature review of early and mid-term results. *J Cardiovasc Surg (Torino).* 2009; 50(4):439-445.
26. Demetriades D, Velmahos GC, Scalea TM, et al. Diagnosis and treatment of blunt thoracic aortic injuries: changing perspectives. *J Trauma.* 2008; 64(6):1415-1418; discussion 1418-1419.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

27. De Rango P, Verzini F, Parlani G, et al. Quality of life in patients with small abdominal aortic aneurysm: the effect of early endovascular repair versus surveillance in the CAESAR trial. *Eur J Vasc Endovasc Surg.* 2011; 41(3):324-331.
28. Dettler C, Demal TJ, Bax L, et al. Simplified frozen elephant trunk technique for combined open and endovascular treatment of extensive aortic diseases. *Eur J Cardiothorac Surg.* 2019; 56(4):738-745.
29. Di X, Ye W, Liu CW, et al. Fenestrated endovascular repair for pararenal abdominal aortic aneurysms: a systematic review and meta-analysis. *Ann Vasc Surg.* 2013; 27(8):1190-1200.
30. Dick F, Hinder D, Immer FF, et al. Outcome and quality of life after surgical and endovascular treatment of descending aortic lesions. *Ann Thorac Surg.* 2008; 85(5):1605-1612.
31. Dumfarth J, Michel M, Schmidli J, et al. Mechanisms of failure and outcome of secondary surgical interventions after thoracic endovascular aortic repair (TEVAR). *Ann Thorac Surg.* 2011; 91(4):1141-1146.
32. Eagleton MJ, Follansbee M, Wolski K, et al. Fenestrated and branched endovascular aneurysm repair outcomes for type II and III thoracoabdominal aortic aneurysms. *J Vasc Surg.* 2016; 63(4):930-942.
33. Egorova N, Giacovelli JK, Greco G, et al. National outcomes for the treatment of ruptured abdominal aortic aneurysm: comparison of open versus endovascular repair. *J Vasc Surg.* 2008; 48(5):1092-1100.
34. Elefteriades JA, Farkas EA. Thoracic aortic aneurysm clinically pertinent controversies and uncertainties. *J Am Coll Cardiol.* 2010; 55(9):841-857.
35. Espinosa G, Ribeiro Alves M, et al. A 10-year single-center prospective study of endovascular abdominal aortic aneurysm repair with the Talent stent-graft. *J Endovasc Ther.* 2009; 16(2):125-135.
36. Fairman RM, Criado F, Farber M, et al. Pivotal results of the Medtronic Vascular Talent Thoracic Stent Graft System: the VALOR trial. *J Vasc Surg.* 2008; 48(3):546-554.
37. Farber MA1, Giglia JS, Starnes BW, et al. Evaluation of the redesigned conformable GORE TAG thoracic endoprosthesis for traumatic aortic transection. *J Vasc Surg.* 2013; 58(3):651-658.
38. Foster J, Ghosh J, Baguneid M. In patients with ruptured abdominal aortic aneurysm does endovascular repair improve 30-day mortality? *Interact Cardiovasc Thorac Surg.* 2010; 10(4):611-619.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

39. Franks SC, Sutton AJ, Bown MJ, Sayers RD. Systematic review and meta-analysis of 12 years of endovascular abdominal aortic aneurysm repair. *Eur J Vasc Endovasc Surg.* 2007; 33(2):154-171.
40. Frederick JR, Woo YJ. Thoracoabdominal aortic aneurysm. *Ann Cardiothorac Surg.* 2012; 1(3): 277-285.
41. Giles KA, Hamdan AD, Pomposelli FB, et al. Population-based outcomes following endovascular and open repair of ruptured abdominal aortic aneurysms. *J Endovasc Ther.* 2009; 16(5):554-564.
42. Georgiadis GS, van Herwaarden JA, Saengprakai W, et al. Endovascular treatment of complex abdominal and thoracoabdominal type IV aortic aneurysms with fenestrated technology. *J Cardiovasc Surg (Torino).* 2017; 58(4):574-590.
43. Glebova NO, Selvarajah S, Orion KC, et al. Fenestrated endovascular repair of abdominal aortic aneurysms is associated with increased morbidity but comparable mortality with infrarenal endovascular aneurysm repair. *J Vasc Surg.* 2015; 61(3):604-610.
44. Gopaldas RR, Huh J, Dao TK, et al. Superior nationwide outcomes of endovascular versus open repair for isolated descending thoracic aortic aneurysm in 11,669 patients. *J Thorac Cardiovasc Surg.* 2010; 140(5):1001-1010.
45. Greenberg RK, Chuter TAM, Cambria RP, et al. Zenith abdominal aortic aneurysm endovascular graft. *J Vasc Surg.* 2008; 48(1):1-9.
46. Greenberg RK, Haulon S, Lyden SP et al. Endovascular management of juxtarenal aneurysms with fenestrated endovascular grafting. *J Vasc Surg.* 2004; 39(2):279-287.
47. Greenberg RK, Sternbergh WC 3rd, Makaroun M, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. *J Vasc Surg.* 2009; 50(4):730-737, e1.
48. Greenhalgh R, Brown IC, Epstein D, et al. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomized controlled trial. *Lancet.* 2005; 365(9478):2187-2192.
49. Greenhalgh R, Brown IC, Epstein D, et al. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomized controlled trial. *Lancet.* 2005; 365(9478):2179-2186.
50. Greenhalgh RM, Brown LC, Powell JT, et al. Endovascular versus open repair of abdominal aortic aneurysm. *N Engl J Med.* 2010; 362(20):1863-1871.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

51. Greenhalgh RM, Brown LC, Powell JT, et al.; UK EVAR Trial Investigators. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. *N Engl J Med.* 2010; 362(20):1872-1880.
52. Ham SW, Rowe VL, Ochoa C, et al. Thoracic aortic stent grafting for acute complicated Type B aortic dissections. *Ann Vasc Surg.* 2011; 25(3):333-339.
53. Hanna JM, Andersen ND, Ganapathi AM, et al. Five-year results for endovascular repair of acute complicated type B aortic dissection. *J Vasc Surg.* 2014; 59(1):96-106.
54. Hinchliffe RJ, Bruijstens L, MacSweeney ST, et al. A randomized trial of endovascular and open surgery for ruptured abdominal aortic aneurysm - results of a pilot study and lessons learned for future studies. *Eur J Vasc Endovasc Surg.* 2006; 32(5):506-513.
55. Hu Z, Li Y, Peng R, et al. Multi-branched stent-grafts for the treatment of thoracoabdominal aortic aneurysms: a systematic review and meta-analysis. *J Endovasc Ther.* 2016; 23(4):626-633.
56. IMPROVE Trial Investigators. Endovascular strategy or open repair for ruptured abdominal aortic aneurysm: one-year outcomes from the IMPROVE randomized trial. *Eur Heart J.* 2015; 36(31):2061-2069.
57. Ius F, Fleissner F, Pichlmaier M, et al. Total aortic arch replacement with the frozen elephant trunk technique: 10-year follow-up single-center experience. *Eur J Cardiothorac Surg.* 2013; 44(5):949-957.
58. Jean-Baptiste E, Batt M, Azzaoui R, et al. A comparison of the mid-term results following the use of bifurcated and aorto-uni-iliac devices in the treatment of abdominal aortic aneurysms. *Eur J Vasc Endovasc Surg.* 2009; 38(3):298-304.
59. Jonker FH, Trimarchi S, Verhagen HJ, et al. Meta-analysis of open versus endovascular repair for ruptured descending thoracic aortic aneurysm. *J Vasc Surg.* 2010; 51(4):1026-1032, 32 e1-32 e2.
60. Jordan WD Jr, Moore WM Jr, Melton JG, et al. Secure fixation following EVAR with the Powerlink XL System in wide aortic necks: results of a prospective, multicenter trial. *J Vasc Surg.* 2009; 50(5):979-986.
61. Kang WC, Greenberg RK, Mastracci TM, et al. Endovascular repair of complicated chronic distal aortic dissections: intermediate outcomes and complications. *J Thorac Cardiovasc Surg.* 2011; 142(5):1074-1083.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

62. Kang WC, Shin EK, Park CH, et al. Hybrid endovascular repair for aortic arch pathology: intermediate outcomes and complications: a retrospective analysis. *Catheter Cardiovasc Interv*. 2013; 82(2):275-282.
63. Khoynezhad A, Donayre CE, Azizzadeh A, et al.; RESCUE investigators. One-year results of thoracic endovascular aortic repair for blunt thoracic aortic injury (RESCUE trial). *J Thorac Cardiovasc Surg*. 2015; 149(1):155-161.
64. Kieffer WK, Sonnenberg S, Windhaber RA, et al. Complications and reintervention following elective open abdominal aortic aneurysm repair: a 10-year retrospective analysis. *Ann R Coll Surg Engl*. 2012; 94(3):177-180.
65. Konstantinos GM, Spyridon NM, Dalainas I, et al. Management of complicated and uncomplicated acute type B dissection. A systematic review and meta-analysis. *Ann Cardiothorac Surg*. 2014; 3(3):234-246.
66. Kwolek CJ, Ouriel K, Stucky FS, et al. Five-year results of the LEOPARD trial of commercially available endografts. *J Vasc Surg*. 2023; 78(2):324-332.e2.
67. Lederle FA, Freischlag JA, Kyriakides TC, et al. Outcomes following endovascular vs. open repair of abdominal aortic aneurysm: a randomized trial. *JAMA*. 2009; 302(14):1535-1542.
68. Lederle FA, Freischlag JA, Kyriakides TC, et al.; OVER Veterans Affairs Cooperative Study Group. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. *N Engl J Med*. 2012; 367(21):1988-1997.
69. Li Y, Hu Z, Bai C, et al. Fenestrated and chimney technique for juxtarenal aortic aneurysm: a systematic review and pooled data analysis. *Sci Rep*. 2016; 6:20497.
70. Liang NL, Reitz KM, Makaroun MS, et al. Comparable perioperative mortality outcomes in younger patients undergoing elective open and endovascular abdominal aortic aneurysm repair. *J Vasc Surg*. 2018; 67(5):1404-1409.
71. Lovegrove RE, Javid M, Magee TR, Galland RB. Meta-analysis of 21,178 patients undergoing open or endovascular repair of abdominal aortic aneurysm. *Br J Surg*. 2008; 95(6):677-684.
72. Luebke T, Brunkwall J. Outcome of patients with open and endovascular repair in acute complicated Type B aortic dissection: a systematic review and meta-analysis of case series and comparative studies. *J Cardiovasc Surg (Torino)*. 2010; 51(5):613-632.
73. Lyden SP. Commentary on fenestrated and branched stent grafts. *Perspect Vasc Surg Endovasc Ther*. 2008; 20(2):188-189.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

74. Makaroun MS, Dillavou ED, Kee ST, et al. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. *J Vasc Surg.* 2005; 41(1):1-9.
75. Makaroun MS, Dillavou ED, Wheatley GH, et al. Five-year results of endovascular treatment with the Gore TAG device compared with open repair of thoracic aortic aneurysms. *J Vasc Surg.* 2008; 47:912-918.
76. Manunga JM, Cragg A, Garberich R, et al. Preoperative inferior mesenteric artery embolization: a valid method to reduce the rate of type II endoleak after EVAR? *Ann Vasc Surg.* 2017; 39:40-47.
77. Martin G, Riga C, Gibbs R, et al. Short- and long-term results of hybrid arch and proximal descending thoracic aortic repair: a benchmark for new technologies. *J Endovasc Ther.* 2016; 23(5):783-790.
78. Matsumoto AH, Angle JF, Secic M, et al. Secondary procedures following thoracic aortic stent grafting in the first 3 years of the VALOR test and VALOR II trials. *J Vasc Interv Radiol.* 2014; 25(5):685-692.
79. Matsumura JS, Cambria RP, Dake MD, et al. International controlled clinical trial of thoracic endovascular aneurysm repair with the Zenith TX2 endovascular graft: 1-year results. *J Vasc Surg.* 2008; 47(2):247-257; discussion 257.
80. Matsumura JS, Melissano G, Cambria RP, et al. Five-year results of thoracic endovascular aortic repair with the Zenith TX2. *J Vasc Surg.* 2014; 60(1):1-10.
81. McCarthy A, Gray J, Sastry P, et al. Systematic review of endovascular stent grafting versus open surgical repair for the elective treatment of arch/descending thoracic aortic aneurysms. *BMJ Open.* 2021; 11(3):e043323.
82. McPhee J, Eslami MH, Arous EJ, et al. Endovascular treatment of ruptured abdominal aortic aneurysms in the United States (2001-2006): a significant survival benefit over open repair is independently associated with increased institutional volume. *J Vasc Surg.* 2009; 49(4):817-826.
83. Motta F, Parodi FE, Knowles M, et al. Performance of Viabahn balloon-expandable stent compared with self-expandable covered stents for branched endovascular aortic repair. *J Vasc Surg.* 2021; 73(2):410-416.
84. Moulakakis KG, Mylonas SN, Dalainas I, et al. Management of complicated and uncomplicated acute type B dissection. A systematic review and meta-analysis. *Ann Cardiothorac Surg.* 2014; 3(3):234-246.

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

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Current Effective Date: 09/09/2024

85. Moulakakis KG, Mylonas SN, Markatis F, et al. A systematic review and meta-analysis of hybrid aortic arch replacement. *Ann Cardiothorac Surg.* 2013; 2(3):247-260.
86. Muhs BE, Verhoeven EL, Zeebregts CJ, et al. Mid-term results of endovascular aneurysm repair with branched and fenestrated endografts. *J Vasc Surg.* 2006; 44(1):9-15.
87. Murad MH, Rizvi AZ, Malgor R, et al. Comparative effectiveness of the treatments for thoracic aortic transaction. *J Vasc Surg.* 2011; 53(1):193-199. e1-21.
88. Nakamura K, Matsuyama M, Yano M, et al. Open surgery or stent repair for descending aortic diseases: Results and risk factor analysis. *Scand Cardiovasc J.* 2009; 43(3):201-207.
89. Naughton PA, Park MS, Morasch MD, et al. Emergent repair of acute thoracic aortic catastrophes: a comparative analysis. *Arch Surg.* 2012; 147(3):243-249.
90. Nienaber CA. Influence and critique of the INSTEAD Trial (TEVAR versus medical treatment for uncomplicated type B aortic dissection). *Semin Vasc Surg.* 2011; 24(3):167-171.
91. Nienaber CA, Kische S, Akin I, et al. Strategies for subacute/chronic type B aortic dissection: the Investigation of Stent Grafts in Patients with type B Aortic Dissection (INSTEAD) trial 1-year outcome. *J Thorac Cardiovasc Surg.* 2010; 140(6 Suppl):S101-S108; discussion S142-S146.
92. Nienaber CA, Rousseau H, Eggebrecht H, et al. Randomized comparison of strategies for type B aortic dissection: the INInvestigation of STEnt Grafts in Aortic Dissection (INSTEAD) trial. *Circulation.* 2009; 120(25):2519-2528.
93. Nordon IM, Hinchliffe RJ, Holt PJ, et al. Modern treatment of juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair--a systematic review. *Eur J Vasc Endovasc Surg.* 2009; 38(1):35-41.
94. Oderich GS, Farber MA, Schneider D, et al. Final 5-year results of the United States Zenith Fenestrated prospective multicenter study for juxtarenal abdominal aortic aneurysms. *J Vasc Surg.* 2021; 73(4):1128-1138.
95. O'Donnell TFX, Boitano LT, Deery SE, et al. Open versus fenestrated endovascular repair of complex abdominal aortic aneurysms. *Ann Surg.* 2019; 69(5):1421-1428.
96. Orandi BJ, Dimick JB, Deeb GM, et al. A population-based analysis of endovascular versus open thoracic aortic aneurysm repair. *J Vasc Surg.* 2009; 49(5):1112-1116.
97. Ouriel K, Clair DG, Kent KC, et al. Endovascular repair compared with surveillance for patients with small abdominal aortic aneurysms. *J Vasc Surg.* 2010; 51(5):1081-1087.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

98. Parsa CJ, Williams JB, Bhattacharya SD, et al. Midterm results with thoracic aortic endovascular repair for chronic Type B aortic dissection with associated aneurysm. *J Thorac Cardiovasc Surg.* 2011; 141(2):322-327.
99. Patel HJ, Hemmila MR, Williams DM, et al. Late outcomes following open and endovascular repair of blunt thoracic aortic injury. *J Vasc Surg.* 2011; 53(3):615-621.
100. Patel R, Sweeting MJ, Powell JT, Greenhalgh RM.; EVAR trial investigators. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomized controlled trial. *Lancet.* 2016; 388(10058):2366-2374.
101. Patel HJ, Williams DM, Upchurch GR Jr, et al. A comparative analysis of open and endovascular repair for the ruptured descending thoracic aorta. *J Vasc Surg.* 2009; 50(6):1265-1270.
102. Peppelenbosch N, Geelkerken RH, Soong C, et al. Endograft treatment of ruptured abdominal aortic aneurysms using the Talent aorto-uni-iliac system: an international multicenter study. *J Vasc Surg.* 2006; 43(6):1111-1123.
103. Prinssen M, Verhoeven LG, Buth J, et al.; Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial Group. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. *N Engl J Med.* 2004; 351(16):1607-1618.
104. Qi RD, Zhu JM, Liu YM, et al. Frozen elephant trunk for acute type B dissection involving the distal arch in the hybrid repair era. *Ann Thorac Surg.* 2018; 106(4):1182-1188.
105. Reilly LM, Chuter TA. Endovascular repair of thoracoabdominal aneurysms: design options, device construct, patient selection and complications. *J Cardiovasc Surg (Torino).* 2009; 50(4):447-460.
106. Ricotta JJ, Oderich GS. Fenestrated and branched stent grafts. *Perspect Vasc Surg Endovasc Ther.* 2008; 20(2):174-187.
107. Sachs T, Pomposelli F, Hagberg R, et al. Open and endovascular repair of type B aortic dissection in the nationwide inpatient sample. *J Vasc Surg.* 2010; 52(4):860-866; discussion 866.
108. Schermerhorn ML, O'Malley AJ, Jhaveri A, et al. Endovascular vs. open repair of abdominal aortic aneurysms in the Medicare population. *N Engl J Med.* 2008; 358(5):464-474.
109. Schwarze ML, Shen Y, Hemmerich J, Dale W. Age-related trends in utilization and outcome of open and endovascular repair for abdominal aortic aneurysm in the United States, 2001-2006. *J Vasc Surg.* 2009; 50(4):722-729.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

110. Shi E, Gu T, Yu Y, et al. Early and midterm outcomes of hemiarach replacement combined with stented elephant trunk in the management of acute DeBakey type I aortic dissection: comparison with total arch replacement. *J Thorac Cardiovasc Surg.* 2014; 148(5):2125-2131.
111. Starnes BW, Dwivedi AJ, Giglia JS, et al.; TRANSFIX Study Investigators. Endovascular repair for blunt thoracic aortic injury using the Zenith Alpha low-profile device. *J Vasc Surg.* 2015; 62(6):1495-503.
112. Starnes BW, Dwivedi A, Giglia J, et al; TRANSFIX Study Investigators. Updated outcomes from the TRANSFIX study to evaluate endovascular repair of blunt thoracic aortic injuries with the Zenith Alpha thoracic device. *J Vasc Surg.* 2020; 71(6):1851-1857.
113. Steuer J, Eriksson MO, Nyman R, et al. Early and long-term outcome after thoracic endovascular aortic repair (TEVAR) for acute complicated Type B aortic dissection. *Eur J Vasc Endovasc Surg.* 2011; 41(30):318-323.
114. Svensson LG, Rushing GD, Valenzuela ES, et al. Modifications, classification, and outcomes of elephant-trunk procedures. *Ann Thorac Surg.* 2013; 96(2):548-558.
115. Sweeting MJ, Patel R, Powell JT, et al. Endovascular repair of abdominal aortic aneurysm in patients physically ineligible for open repair: very long-term follow-up in the EVAR-2 randomized controlled trial. *Ann Surg.* 2017; 266(5):713-719.
116. Takagi H, Umemoto T.; ALICE Group. A meta-analysis of total arch replacement with frozen elephant trunk in acute type A aortic dissection. *Vasc Endovascular Surg.* 2016; 50(1):33-46.
117. Thrumurthy SG, Karthikesalingam A, Patterson BO, et al. A systematic review of mid-term outcomes of thoracic endovascular repair (TEVAR) of chronic type B aortic dissection. *Eur J Vasc Endovasc Surg.* 2011; 42(5):632-647.
118. Tian DH, Wan B, Di Eusano M, et al. A systematic review and meta-analysis on the safety and efficacy of the frozen elephant trunk technique in aortic arch surgery. *Ann Cardiothorac Surg.* 2013; 2(5):581-591.
119. Tsagakis K, Wendt D, Dimitriou AM, et al. The frozen elephant trunk treatment is the operation of choice for all kinds of arch disease. *J Cardiovasc Surg (Torino).* 2018; 59(4):540-546.
120. Ullery BW, Cheung AT, Fairman RM, et al. Risk factors, outcomes and clinical manifestations of spinal cord ischemia following thoracic endovascular aortic repair. *J Vasc Surg.* 2011; 54(3):677-684.
121. Ultee KHJ, Zettervall SL, Soden PA, et al. The impact of endovascular repair on management and outcome of ruptured thoracic aortic aneurysms. *J Vasc Surg.* 2017; 66(2):343-352.

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Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

122. Ulug P, Sweeting MJ, von Allmen RS, et al. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis. *Lancet*. 2017; 389(10088):2482-2491.
123. van Beek SC, Conijn AP, Koelemay MJ, et al. Editor's Choice - Endovascular aneurysm repair versus open repair for patients with a ruptured abdominal aortic aneurysm: a systematic review and meta-analysis of short term survival. *Eur J Vasc Endovasc Surg*. 2014; 47(6):593-602.
124. Verhoeven EL, Vourliotakis G, Bos WT, et al. Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-center experience. *Eur J Vasc Endovasc Surg*. 2010; 39(5):529-536.
125. Verhoeven ELG, Katsargyris A, Bekkema F, et al. Ten-year experience with endovascular repair of thoracoabdominal aortic aneurysms: results from 166 consecutive patients. *Eur J Vasc Endovasc Surg* 2015; 49(5):524-531.
126. VIRTUE Registry Investigators. The VIRTUE registry of Type B thoracic dissections – study design and early results. *Eur J Vasc Endovasc Surg*. 2011; 41(2):159-166.
127. von Meijenfeldt GC, Alberga AJ, Balm R, et al. Results from a nationwide prospective registry on open surgical or endovascular repair of juxtarenal abdominal aortic aneurysms. *J Vasc Surg*. 2022; 75(1):81-89.
128. Voskresensky I, Scali ST, Feezor RJ, et al. Outcomes of thoracic endovascular aortic repair using aortic arch chimney stents in high-risk patients. *J Vasc Surg*. 2017; 66(1):9-20.
129. Wang SK, Gutwein AR, Gupta AK, et al. Institutional experience with the Zenith Fenestrated aortic stent graft. *J Vasc Surg*. 2018; 68(2):331-336.
130. Wheatley III GH, Gurbuz AT, Rodriguez-Lopez JA, et al. Midterm outcome in 158 consecutive Gore TAG thoracic endoprostheses: single center experience. *Ann Thorac Surg*. 2006; 81(5):1570-1577.
131. Xenos ES, Minion DJ, Davenport DL, et al. Endovascular versus open repair for descending thoracic aortic rupture: institutional experience and meta-analysis. *Eur J Cardiothorac Surg*. 2009; 35(2):282-286.
132. Yaoguo Y, Zhong C, Lei K, Yaowen X. Treatment of complex aortic aneurysms with fenestrated endografts and chimney stent repair: Systematic review and meta-analysis. *Vascular*. 2017; 25(1):92-100.

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Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

133. Yokoyama Y, Kuno T, Takagi H, et al. Meta-analysis of phase-specific survival after elective endovascular versus surgical repair of abdominal aortic aneurysm from randomized controlled trials and propensity score-matched studies. *J Vasc Surg.* 2020; 72(4):1464-1472.
134. Zeeshan A, Woo EY, Bavaria JE, et al. Thoracic endovascular aortic repair for acute complicated type B aortic dissection: superiority relative to conventional open surgical and medical therapy. *J Thorac Cardiovasc Surg.* 2010; 140(6 Suppl):S109-115; discussion S142-S146.
135. Zhang H, Wang ZW, Zhou Z, et al. Endovascular stent-graft placement or open surgery for the treatment of acute type B aortic dissection: a meta-analysis. *Ann Vasc Surg.* 2012; 26(4):454-461.
136. Zhong YL, Qi RD, Ma WG, et al. Frozen elephant trunk with modified en bloc arch reconstruction and left subclavian transposition for chronic type A dissection. *J Thorac Dis.* 2018; 10(9):5376-5383.
137. Zipfel B, Czerny M, Funovics M, et al. Endovascular treatment of patients with Type A and B thoracic aortic dissection using relay thoracic stent grafts: results from the RESTORE patient registry. *J Endovasc Ther.* 2011; 18(2):131-143.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Abel D, Morales JP. Society for Vascular Surgery® Documents: Food and Drug Administration commentary on the SVS master file for acute complicated type B aortic dissections and transections. *J Vasc Surg.* 2011; 53(4):1079-1081.
2. Abraha I, Romagnoli C, Montedori A, et al. Thoracic stent graft versus surgery for thoracic aneurysm. *Cochrane Database Syst Rev.* 2016;(6):CD006796.
3. Badger S, Forster R, Blair PH, et al. Endovascular treatment for ruptured abdominal aortic aneurysm. *Cochrane Database Syst Rev.* 2017;(7):CD005261.
4. Bossone E1, LaBounty TM2, Eagle KA2. Acute aortic syndromes: diagnosis and management, an update. *Eur Heart J.* 2018; 39(9):739-749.
5. Brewster DC, Cronenwett JI, Hallett JW, et al. Guidelines for the treatment of abdominal aortic aneurysms. Report of a subcommittee of the Joint Council of the American Association for Vascular Surgery and Society for Vascular Surgery. *J Vasc Surg.* 2003; 37(5):1106-1117.
6. British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry. Early results of fenestrated

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

- endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. *Circulation*. 2012; 125(22):2707-2715.
7. Chaikof EL, Brewster DC, Dalman RL, et al.; Society for Vascular Surgery. The care of patients with an abdominal aortic aneurysm: the Society for Vascular Surgery practice guidelines. *J Vasc Surg*. 2009; 50(4 Suppl):S2-49.
 8. Chaikof EL, Dalman RL, Eskandari MK, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg*. 2018; 67(1):2-77.
 9. Coady MA, Ikonomidis JS, Cheung AT, et al. American Heart Association Council on Cardiovascular Surgery and Anesthesia and Council on Peripheral Vascular Disease. Surgical management of descending thoracic aortic disease: Open and endovascular approaches: a scientific statement from the American Heart Association. *Circulation*. 2010; 121(25):2780-2804.
 10. Cook Research Inc. Zenith[®] p-Branch[®] and Zenith[®] Fenestrated AAA Endovascular Graft Clinical Study (FENP). NLM Identifier: NCT01652235. Last updated December 8, 2022. Available at: <https://clinicaltrials.gov/ct2/show/NCT01652235?cond=NCT01652235&rank=1>.
 11. Cook Research Inc. TRANSFIX Zenith[®] Transection Clinical Study (TRANSFIX). NLM Identifier: NCT 01688050. Last updated Nov. 18, 2020. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT01688050?term=NCT01688050&rank=1>.
 12. Dake MD, White RA, Diethrich EB, et al. Report on endograft management of traumatic thoracic aortic transections at 30 days and 1 year from a multidisciplinary subcommittee of the Society for Vascular Surgery Outcomes Committee. *J Vasc Surg*. 2011; 53(4):1091-1096.
 13. Duffy JMN, Rolph R, Clough RE, et al. Stent graft types for endovascular repair of abdominal aortic aneurysms. *Cochrane Database Syst Rev*. 2013;(3):CD008447.
 14. Erbel R, Aboyans V, Boileau C, et al. 2014 ESC Guidelines on the diagnosis and treatment of aortic diseases: Document covering acute and chronic aortic diseases of the thoracic and abdominal aorta of the adult. The Task Force for the Diagnosis and Treatment of Aortic Diseases of the European Society of Cardiology (ESC). *Eur Heart J*. 2014; 35(41):2873-2926. Available at: <https://academic.oup.com/eurheartj/article/35/41/2873/407693>.
 15. Filardo G, Powell JT, Martinez MA, et al. Surgery for small asymptomatic abdominal aortic aneurysms. *Cochrane Database Syst Rev*. 2012;(3):CD001835.
 16. Grabenwoger M, Alfonso F, Bachet J, et al. Thoracic Endovascular Aortic Repair (TEVAR) for the treatment of aortic diseases: a position statement from the European Association for Cardio-

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Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *Eur Heart J*. 2012; 33(13):1558-1563.

17. Guirguis-Blake JM, Beil TL, Senger CA, et al. Primary Care Screening for Abdominal Aortic Aneurysm. Updated Evidence Report and Systematic Review for the US Preventive Services Task Force (USPSTF). *JAMA*. 2019; 322(92):2219-2238.
18. Hiratzka LF, Bakris GL, Beckman JA, et al. 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the diagnosis and management of patients with thoracic aortic disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, American Association for Thoracic Surgery, American College of Radiology, American Stroke Association, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of Thoracic Surgeons, and Society for Vascular Medicine. *J Am Coll Cardiol*. 2010; 55(14):e27-e129.
19. Hirsh AT, Haskal ZJ, Hertzner NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine and Biology, and the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2006; 47(6):1239-1312.
20. Isselbacher EM, Preventza O, Hamilton Black J 3rd, et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022; 146(24):e334-e482.
21. Lee WA, Matsumura JS, Mitchell RS, et al. Endovascular repair of traumatic thoracic aortic injury: clinical practice guidelines of the Society for Vascular Surgery. *J Vasc Surg*. 2011; 53(1):187-192.
22. Lombardi JV, Gleason TG, Panneton JM, et al.; STABLE II Investigators. STABLE II clinical trial on endovascular treatment of acute, complicated type B aortic dissection with a composite device design. *J Vasc Surg*. 2020; 71(4):1077-1087.e2.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

23. National Institute for Health and Care Excellence (NICE). Abdominal aortic aneurysm: diagnosis and management. NICE guideline [NG156]. March 19, 2020. <https://www.nice.org.uk/guidance/ng156>
24. Oderich GS, Forbes TL, Chaer R, et al. Society for Vascular Surgery (SVS). Reporting standards for endovascular aortic repair of aneurysms involving the renal-mesenteric arteries. SVS Reporting Standards. 2021; 73(1):Suppl 4S-52S.
25. Rokosh RS, Starnes BW, Chaikof EL. Society for Vascular Surgery (SVS). Implementation of clinical practice guidelines for patients with an abdominal aortic aneurysm: Repair of an abdominal aortic aneurysm. J Vasc Surg. 2021; 73(5):1485-1487.
26. Svensson LG, Kouchoukos NT, Miller DC, et al.; Society of Thoracic Surgeons Endovascular Surgery Task Force. Expert consensus document on the treatment of descending thoracic aortic disease using endovascular stent-grafts. Ann Thorac Surg. 2008; 85(1 Suppl):S1-S41.
27. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Ovation Abdominal Stent Graft System, TriVascular, Inc. No. 11100008. Rockville, MD: FDA. November 1, 2011. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf10/h100008a.pdf.
28. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). GORE TAG Thoracic Endoprosthesis, W.L. Gore and Associates. Summary of Safety and Effectiveness. No. P040043. Rockville, MD: FDA. March 23, 2005. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/p040043b.pdf.
29. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH): Ancure[®] Aortoiliac System, Guidant Corporation. Summary of Safety and Effectiveness. No. 990017/S030. Rockville, MD: FDA. April 24, 2002. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/p990017s030b.pdf.
30. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Endologix PowerLink[®] System, Endologix, Inc. Summary of Safety and Effectiveness. No. P040002. Rockville, MD: FDA. October 29, 2004. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf4/p040002b.pdf.
31. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Zenith[®] Alpha[™] Thoracic Endovascular Graft, Cook, Inc. Summary of Safety and Effectiveness. No. P140016. Rockville, MD: FDA. September 15, 2015. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P140016>.

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Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

32. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). The Zenith TX2 Thoracic TAA Endovascular Graft with the H&LB One-Shot Introduction System, Cook, Inc. Summary of Safety and Effectiveness. No. P070016. Rockville, MD: FDA. May 21, 2008. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf7/p070016b.pdf.
33. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). The Talent Thoracic Stent Graft System, Medtronic Vascular, Inc. Summary of Safety and Effectiveness. No. P070007. Rockville, MD: FDA. June 5, 2008. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070007a.pdf.
34. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Valiant® Thoracic Stent Graft with the Captivia Delivery System, Medtronic Vascular, Inc. Summary of Safety and Effectiveness. No. P100040/S008. Rockville, MD: FDA. October 26, 2012. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf10/p100040s008b.pdf. Expanded indications. P100040/S012. February 4, 2014. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100040S012>.
35. United States Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Zenith® Fenestrated AAA Endovascular Graft (with the adjunctive Zenith Alignment Stent). Cook, Inc. Summary of Safety and Effectiveness. No. P020018/S040. Rockville, MD: FDA. April 11, 2012. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf2/p020018s040a.pdf.
36. Upchurch GR, Escobar GA, Azizzadeh A, et al. Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms. J Vasc Surg. 2021; 73(1S):55S-83S.
37. Wang Q, Wu J, Ma Y, et al. Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair. Cochrane Database of Systematic Reviews 2023, No.:CD010185. Available at <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010185.pub4/full>.
38. Walker TG, Kalva SP, Yeddula K, et al. Clinical practice guidelines for endovascular abdominal aortic aneurysm repair: written by the Standards of Practice Committee for the Society of Interventional Radiology and endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association. J Vasc Interv Radiol. 2010; 21(11):1632-1655.

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39. White RA, Miller C, Criado FJ, et al. Report on the results of thoracic endovascular aortic repair for acute, complicated, Type B aortic dissection at 30 days and 1 year from a multidisciplinary subcommittee of the Society for Vascular Surgery Outcomes Committee. *J Vasc Surg.* 2011; 53(4):1082-1090.
40. Wilt TJ, Lederle FA, Macdonald R, et al. Comparison of endovascular and open surgical repairs for abdominal aortic aneurysm. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). *Evid Rep Technol Assess* 144 (Full Rep). 2006; (144):1-113.
41. Zettervall SL, Dansey K, Kline B, et al. Significant aortic neck dilation occurs after repair of juxtarenal aneurysms with fenestrated endovascular aneurysm repair. NCT01538056. *J Vasc Surg.* 2021; 74(4):1090-1097.

Websites for Additional Information

1. National Library of Medicine. Medical Encyclopedia- Aneurysms. Available at: <http://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v%3Aproject=medlineplus&query=Aneurysm&x=16&y=9>.
2. Society for Vascular Surgery. Abdominal Aortic Aneurysms. Available at: <https://vascular.org/patient-resources/vascular-conditions/abdominal-aortic-aneurysm>.

Policy History

Original Effective Date: 01/27/2003

Current Effective Date: 09/09/2024

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|------------|---|
| 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 |

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Louisiana

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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

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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.

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- 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 revision.
 - 08/01/2024 Medical Policy Committee review
 - 08/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- Next Scheduled Review Date: 08/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

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CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	33880, 33881, 33883, 33884, 33886, 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, 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.

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

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

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

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

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

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

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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