MEDICAL POLICY

POLICY TITLE	**ENDOVASCULAR STENT GRAFTS FOR DISORDERS OF THE THORACIC AORTA**
POLICY NUMBER	**MP 1.132**

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2025**

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I. POLICY

Endovascular stent grafts using devices approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** for the following conditions:

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

Endovascular stent grafts are considered **investigational** for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated aortic dissection as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Endovascular stent grafts are considered **investigational** for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Endograft Placement

Endograft placement relies on non-aneurysmal aortic segments proximal and distal to the aneurysm and/or dissection for anchoring, and a maximal graft diameter that varies by device. For example, the Gore TAG® endoprosthesis is approved by the U.S. Food and Drug Administration (FDA) for "≥2 cm non-aneurysmal aorta proximal and distal to the aneurysm" and an "aortic inner diameter of 23-37 mm." The Zenith TX2® device is approved by the FDA for

non-aneurysmal aortic segments "of at least 25 mm in length" and a "diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm."

Uncomplicated Type B Aortic Dissection with Indication for Intervention

Guidelines generally suggest medical management for most patients with uncomplicated type B aortic dissection. However, guidelines by the American College of Cardiology/American Heart Association (ACC/AHA) and Society of Thoracic Surgeons/American Association for Thoracic Surgery suggest that early, pre-emptive intervention may be considered in patients with uncomplicated acute type B aortic dissection who have high-risk features. The high-risk criteria suggested by ACC/AHA are: maximal aortic diameter >40 mm, false-lumen diameter >20-22 mm, entry tear >10 mm, entry tear on lesser curvature, increase in total aortic diameter of >5 mm between serial imaging studies, bloody pleural effusion, imaging-only evidence of malperfusion, refractory hypertension despite >3 different classes of antihypertensive medications at maximal recommended or tolerated doses, refractory pain persisting >12 hours despite maximal recommended or tolerated doses, or need for readmission. In patients with an indication for early intervention, guidelines suggest endovascular repair may be preferred for patients with suitable anatomy but who are at high risk for complications of open repair due to comorbidities.

Cross-Reference:
MP 1.090 Endovascular Grafts for Abdominal Aortic Aneurysms

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

TOP

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

Thoracic Aortic Aneurysms

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

Treatment

Indications for the elective surgical repair of aortic aneurysms are based on estimates of the prognosis of the untreated aneurysm balanced against the morbidity and mortality of the intervention. The prognosis of thoracic aortic aneurysm (TAA) is typically reported regarding the risk of rupture according to size and location (i.e., the ascending or descending or thoracoabdominal aorta). While several studies have estimated the risk of rupture of untreated aneurysms, these studies have excluded patients who underwent surgical repair; therefore, the true natural history of thoracic aneurysms is unknown. Clouse et al (1998) performed a population-based study of TAA diagnosed in Minnesota, between 1980 and 1994. A total of 133 patients were identified; the primary clinical endpoints were cumulative rupture risk, rupture risk as a function of aneurysm size, and survival. The cumulative risk of rupture was 20% after 5 years. The 5-year risk of rupture as a function of aneurysm size at recognition was 0% for aneurysms less than 4 cm in diameter, 16% for those 4 to 5.9 cm, and 31% for aneurysms 6 cm or more. Interestingly, 79% of the ruptures occurred in women. Davies et al (2002) reported on the yearly rupture or dissection rates in 721 patients with TAA. A total of 304 patients were dissection-free at presentation; their natural history was followed for rupture, dissection, and death. Patients were excluded from analysis once the operation occurred. Not surprisingly, the authors reported that aneurysm size had a profound impact on outcomes. For example, based on their modeling, a patient with an aneurysm exceeding 6 cm in diameter could expect a yearly rate of rupture or dissection of at least 6.9% and a death rate of 11.8%. In a previous report, these same authors suggested surgical intervention of a descending aorta aneurysm if its diameter measured 6.5 cm.

Surgical mortality and morbidity are typically subdivided into emergency and elective repair, with a focus on the incidence and risk of spinal cord ischemia, considered of the most devastating complications, resulting in paraparesis or paraplegia. The operative mortality of surgical repair of aneurysm of the descending and thoracoabdominal aorta is estimated at 6% to 12% and 10% to 15%, respectively, while mortality associated with emergent repair is considerably higher. In elective cases, predictors of operative mortality include renal insufficiency, increasing age, symptomatic aneurysm, presence of dissection, and other comorbidities (e.g., cardiopulmonary or cerebrovascular disease). The risk of paraparesis or paraplegia is estimated at 3% to 15%. Thoracoabdominal aneurysms, larger aneurysms, presence of dissection, and diabetes are

predictors of paraplegia. A number of surgical adjuncts have been explored to reduce the incidence of spinal cord ischemia, including distal aortic perfusion, cerebrospinal fluid drainage, hypothermia with circulatory arrest, and evoked potential monitoring. However, the optimal protective strategy is still uncertain.

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

Thoracic Aortic Dissection

Aortic dissection can be subdivided into type A, which involves the aortic arch, and type B, which is confined to the descending aorta. Dissections associated with obstruction and ischemia can also be subdivided into an obstruction caused by an intimal tear at branch vessel orifices, or by compression of the true lumen by the pressurized false lumen. Type B aortic dissections are classified by acuity (termed as complicated or uncomplicated) and chronicity and are summarized in Table 1.

Table 1. Aortic Dissection Acuity

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

Treatment

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

As noted, type A dissections (involving the ascending aorta) are treated surgically. There is more controversy regarding the optimal treatment of type B dissections (i.e., limited to the descending aorta). In general, chronic, stable type B dissections are managed medically, although some surgeons have recommended a more aggressive approach for younger patients in otherwise good health. When serious complications arise from a type B dissection (i.e., shock or visceral ischemia), surgical intervention is usually indicated. Endovascular intervention has supplanted open repair or medical management alone as first-line treatment for complicated type B aortic dissection as a result of accumulated data indicating reduced morbidity and mortality.

Thoracic Aortic Rupture

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

Treatment

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

Thoracic Endovascular Aneurysm Repair

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

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

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

Outcome Measures

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

REGULATORY STATUS

A number of endovascular grafts are approved by the FDA for use in TAAs (Table 2).

FDA product code: MIH

Table 2. Endovascular Grafts Approved for Use in Thoracic Aortic Aneurysms

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

PMA: premarket approval.

The Gore TAG® Thoracic Endoprosthesis is indicated for endovascular repair of aneurysms of the descending thoracic aorta. Use of this device requires patients to have adequate iliac/femoral access, aortic inner diameter in the range of 23 to 37 mm, and 2 cm or more non-aneurysmal aorta proximal and distal to the aneurysm. In January 2012, the FDA expanded the indication for the Gore TAG® system to include isolated lesions of the thoracic aorta. Isolated lesions refer to aneurysms, ruptures, tears, penetrating ulcers, and/or isolated hematomas, but do not include dissections. Indicated aortic inner diameter is 16 to 42 mm, with 20 mm or more of non-aneurysmal aortic distal and proximal to the lesion.

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

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

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

- Iliac or femoral access vessel morphology compatible with vascular access techniques, devices, and/or accessories
- Non-aneurysmal aortic neck diameter in the range of 19 to 42 mm
- Non-aneurysmal proximal aortic neck length between 15 and 25 mm and non-aneurysmal distal aortic neck length between 25 and 30 mm depending on the diameter stent graft required.

The Relay®Pro system is indicated for treatment of all lesions of the descending thoracic aorta, including Type B dissections and traumatic injuries.

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

- Iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;

- Non-aneurysmal aortic diameter in the range of 18 to 42 mm (fusiform and saccular aneurysms/penetrating ulcers), 18 to 44 mm (blunt traumatic aortic injuries, or 20 to 44 mm (dissections) and;
- Non-aneurysmal aortic proximal and distal neck lengths 20 mm or more (fusiform and saccular aneurysms/penetrating ulcers), and landing zone 20 mm or more proximal to the primary entry tear (blunt traumatic aortic injuries, dissection). The proximal extent of the landing zone must not be dissected.

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

The Valiant Navion™ is a next generation thoracic stent graft system with a modified design of the Valiant Thoracic Stent Graft with Captivia Delivery System. However, unused Valiant Navion thoracic stent graft systems were voluntarily recalled by the manufacturer (Medtronic) in February 2021 due to endoleaks, stent fractures, and stent ring enlargement. The recall occurred due to results of the Valiant Evo Global Clinical Trial which found 3 patients with stent fractures, 2 of whom had confirmed type IIIb endoleaks, and 1 patient death. Further investigation by an independent imaging laboratory found 7 of 87 patients with stent ring enlargement. The manufacturer is conducting further analysis.

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

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have type B (descending) thoracic aortic aneurysms (TAAs) who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. The available nonrandomized comparative studies have consistently reported reduced short-term mortality and morbidity compared with surgical repair. Although these types of studies are subject to selection bias and other methodologic limitations, the consistency of the findings of equivalent or reduced short-term mortality and fewer early complications across populations with different characteristics supports the conclusion that thoracic endovascular aortic repair (TEVAR) is a safer procedure in the short term. The short-term benefits of TEVAR are mitigated by less favorable longer-term outcomes, but longer-term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have uncomplicated type B (descending) thoracic aortic dissections who receive endovascular repair, the evidence includes randomized controlled trials (RCTs),

systematic reviews, and retrospective cohort studies. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. In the INSTEAD trial there were no statistically significant differences between the endovascular and medical groups for OS at 1 year or at 5 years. At 5 years of follow-up, aorta-specific mortality (7% versus 19%) was significantly lower for endovascular versus medical treatment. In the ADSORB trial, there were significantly fewer events of the composite outcome of incomplete/no false lumen thrombosis, aortic dilation, or aortic rupture in the endovascular group in the per protocol analysis, but the trial had several limitations and was not designed for mortality outcomes. An ongoing RCT (NCT02622542) is designed to compare 5-year all-cause mortality for best medical therapy alone versus best medical therapy with thoracic endovascular aortic repair for uncomplicated acute type B aortic dissection. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have complicated type B (descending) thoracic aortic dissections who receive endovascular repair, the evidence includes systematic reviews and nonrandomized comparative studies. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. Systematic reviews of the available nonrandomized comparative studies consistently indicate benefits in early morbidity and mortality with TEVAR relative to open repair, as well as similar or superior long-term survival outcomes compared to open repair or medical management alone. Although these studies carry inherent limitations and the interventions carry complication risks that do not completely overlap, the accrued evidence favors use of TEVAR over open repair in suitable patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have traumatic descending aortic tears or rupture who receive endovascular repair, the evidence includes nonrandomized comparative studies and systematic reviews. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. Systematic reviews of the available nonrandomized comparative studies consistently indicate benefit in early mortality and similar or superior long-term survival outcomes with TEVAR relative to open repair, with low rates of complications requiring reintervention with long-term follow-up. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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

V. DEFINITIONS

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AORTA is the largest artery in the body, originating from the left ventricle of the heart and extending down to the abdomen, where it branches off into two smaller arteries (the common

iliacs). The aorta distributes oxygenated blood to all parts of the body through the systemic circulation. It is usually divided into five segments/sections:

- Ascending aorta—the section between the heart and the arch of aorta
- Arch of aorta—the peak part that looks like an inverted "U"
- Descending aorta—the section from the arch of aorta to the point where it divides into the common iliac arteries
  - Thoracic aorta—the half of the descending aorta above the diaphragm
  - Abdominal aorta—the half of the descending aorta below the diaphragm

STENT refers to any material or device used to hold tissue in place, to maintain open blood vessels, or to provide support for a graft or anastomoses while healing is taking place.

THORACIC refers to the chest or thorax.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes								
33880	33881	33883	33884	33886	33889	34812	75956	75957
75958	75959							

ICD-10-CM Diagnosis Codes	Description
I71.012	Dissection of descending thoracic aorta
I71.019	Dissection of thoracic aorta, unspecified
I71.03	Dissection of thoracoabdominal aorta
I71.10	Thoracic aortic aneurysm, ruptured, unspecified
I71.13	Aneurysm of the descending thoracic aorta, ruptured
I71.20	Thoracic aortic aneurysm, without rupture, unspecified

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X. POLICY HISTORY

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MP 1.132	**06/04/2020 Consensus Review.** No changes to policy statement. References reviewed and updated. Coding reviewed, no changes. FEP variation updated.

POLICY TITLE	ENDOVASCULAR STENT GRAFTS FOR DISORDERS OF THE THORACIC AORTA
POLICY NUMBER	MP 1.132

	08/24/2021 Consensus Review. Policy statement unchanged. Background, Rationale and References updated.
	07/28/2022 Administrative Update. ICD-10 I71.012, I71.019, I71.110, I71.113, I71.120 added. Effective 10/01/2022
	08/22/2022 Consensus Review. Policy statement unchanged. Rationale, references and background update.
	11/10/2023 Consensus Review. Policy statement unchanged. Rationale, references and background update.
	11/01/2024 Consensus Review. No change to policy statement. Policy Guidelines, Background and Rationale updated. References added.

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