MASSACHUSETTS

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Medical Policy

Endovascular Stent Grafts for Disorders of the Thoracic Aorta

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Policy Number: 233

BCBSA Reference Number: 7.01.86 (For Plan internal use only)
NCD/LCD: NA

Related Policies

- Endovascular Stent Grafts for Abdominal Aortic Aneurysms, #098
- Wireless Pressure Sensors in Endovascular Aneurysm, # 306

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Endovascular stent grafts for the treatment of thoracic aortic arch aneurysms[1] may be considered **MEDICALLY NECESSARY**.

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

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

*Endograft placement relies on nonaneurysmal aortic segments proximal and distal to the aneurysm and/or dissection for anchoring, and a maximal graft diameter that varies by device. The Gore TAG® endoprosthesis is approved by the 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 Talent™ Thoracic Stent Graft System is approved by FDA for "non-aneurysmal aortic proximal and distal neck lengths ≥20 mm" and a "non-aneurysmal aortic diameter in the range of 18–42 mm." The Zenith TX2® device is approved by FDA for nonaneurysmal 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."

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.

Endovascular stent grafts are considered **INVESTIGATIONAL** for the treatment of ascending aortic disorders.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
33880	Endovascular repair of descending thoracic aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33881	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin
33883	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); initial extension
33884	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); each additional proximal extension (List separately in addition to code for primary procedure)
33886	Placement of distal extension prosthesis(s) delayed after endovascular repair of descending thoracic aorta
33889	Open subclavian to carotid artery transposition performed in conjunction with endovascular repair of descending thoracic aorta, by neck incision, unilateral
75956	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving

	coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
75957	Endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); not involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
75958	Placement of proximal extension prosthesis for endovascular repair of descending thoracic aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption), radiological supervision and interpretation
75959	Placement of distal extension prosthesis(s) (delayed) after endovascular repair of descending thoracic aorta, as needed, to level of celiac origin, radiological supervision and interpretation

Description

Thoracic Aortic Aneurysms

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 (ie, 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.[1,] 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.[2,] 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.[3,]

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 the most devastating complication, 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.[1,4,] In elective cases, predictors of operative

mortality include renal insufficiency, increasing age, symptomatic aneurysm, the presence of dissection, and other comorbidities (eg, cardiopulmonary or cerebrovascular disease). The risk of paraparesis or paraplegia is estimated at 3% to 15%. Thoracoabdominal aneurysms, larger aneurysms, the presence of dissection, and diabetes are predictors of paraplegia.[5,6,]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.[7,8,9,10,] However, the optimal protective strategy is still uncertain.[11,]

This significant mortality and morbidity risks make 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 patients with smaller symptomatic aneurysms.

Thoracic Aortic Dissection

Aortic dissection can be subdivided into type A, which involves the aortic arch, and type B, which is confined to the descending aorta. Dissections associated with obstruction and ischemia can also be subdivided into an obstruction caused by an intimal tear at branch vessel orifices, or by compression of the true lumen by the pressurized false lumen.

Treatment

Type A dissections 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 (ie, 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 (ie, shock or visceral ischemia), surgical intervention is usually indicated. Although there is an estimated 1-year survival rate of 50% in those treated with an open surgical procedure, it is not clear whether that rate is any better or worse for those treated medically.[12,] The advent of stent grafting, with the potential of reducing the mortality of an open surgical procedure, may further expand the number of patients considered for surgical intervention.

Thoracic Aortic Rupture

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

Treatment

Emergent repair of thoracic artery rupture is indicated in many cases in which there is free bleeding into the mediastinum and/or complete transection of the aortic wall. In some cases of aortic rupture, where the aortic media and adventitia are intact, watchful waiting with delayed surgical intervention is a treatment option. With the advent of thoracic endovascular aortic 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 Aortic 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 a 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 (eg, paraplegia, cardiopulmonary events), and others are unique to TEVAR (eg, 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.

Summary

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.

For individuals who have type B (descending) 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 TEVAR is a safer procedure in the short term. The likely short-term benefits of TEVAR are mitigated by less favorable longer-term outcomes, but longer-term mortality appears to be roughly similar for patients undergoing TEVAR or open surgery. The evidence is sufficient to determine 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 with longer follow up. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. For acute, uncomplicated type B dissections, a systematic review demonstrated that the risk of late all-cause mortality was reduced with TEVAR versus best medical management; however, the authors did not quantify the time frame for late outcomes. An RCT has

reported short-term improvements in aortic remodeling and a decreased risk of aortic dilation and rupture in patients treated with TEVAR compared with best medical management. However, this trial was underpowered to evaluate mortality differences, and limitations included a high TEVAR failure rate based on imaging follow-up. In addition, a retrospective study that evaluated a matched population of patients found increased rates of early adverse events with TEVAR compared to best medical management; however, survival rates were significantly improved with TEVAR versus best medical therapy at 1, 3, and 5 years, and aortic rupture rates were significantly reduced with TEVAR at these time points as well. For chronic, uncomplicated type B dissections, evidence from an RCT did not demonstrate short-term outcome benefits associated with TEVAR; however, after more than 5 years of follow-up, TEVAR was associated with a survival benefit beginning 2 years postprocedure. In a systematic review of mostly noncomparative studies, cumulative all-cause early mortality was lower with TEVAR compared with open surgery, but 1-year and 3-year survival rates were similar between the 2 procedures. 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. Short- and intermediate-term results from a systematic review of observational studies that compared TEVAR with open surgery have suggested a benefit for TEVAR in complicated (organ or limb ischemia or rupture) type B dissection. In another systematic review, the rate of survival and freedom from all secondary reinterventions at 10 years was 69.7% and 60.9%, respectively. In a propensity-matched study, an early survival advantage was demonstrated for patients treated with TEVAR compared with best medical management. However, the choice of medical management or TEVAR was based on presenting illness, therefore, the groups were not balanced at baseline, which raises uncertainty about the results. The evidence is insufficient 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. For traumatic thoracic aortic injury and rupture, nonrandomized comparative data have suggested a benefit for TEVAR in reducing periprocedural mortality and morbidity. Although it is expected that RCTs will be difficult to conduct for this indication (due to its emergent nature), the risks of bias in the available nonrandomized studies are high, raising uncertainty about results. The evidence is insufficient 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.

Policy History

Date	Action
8/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2018	Annual policy review.

	Policy clarified. New investigational indications described. Effective 10/1/2018.
6/2017	Annual policy review. New references added.
7/2016	Annual policy review. New references added.
12/2015	Clarified coding information.
11/2015	Added coding language.
8/2015	Annual policy review. New references added.
9/2014	Annual policy review. New references added.
7/2014	Clarified coding information.
1/2014	Annual policy review. New medically necessary indications described. Effective 1/1/2014.
12/2013	Removed ICD-9 diagnosis codes 441.01, 441.03, 441.1, 441.2, 441.6, and 441.7 as the policy requires prior authorization.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
5/2011	Annual policy review. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
6/1/2010	New policy, effective 6/1/2010, describing covered and non-covered indications.
12/2009	Annual policy review. No changes to policy statements.
5/2008	Annual policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion