02-33000-29

Original Effective Date: 04/15/03

Reviewed: 09/26/24

Revised: 10/15/24

Subject: Endovascular Stent Grafts for Disorders of the Thoracic Aorta

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

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.

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. 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. 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. 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.

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. 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.A number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) for use in TAAs.

Summary and Analysis of Evidence: The evidence for endovascular repair of type B (descending) TAAs includes nonrandomized comparative studies and systematic reviews. 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 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. Individuals with uncomplicated type B (descending) thoracic aortic dissections who receive endovascular repair, the evidence includes randomized controlled trials (RCTs) , systematic reviews, and retrospective cohort studies. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. The evidence for individuals with complicated type B (descending) thoracic aortic dissections who receive endovascular repair, the evidence includes systematic reviews and nonrandomized comparative studies. 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. 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. Ascending aortic disorders treated with endovascular repair, the evidence includes small case series. The use of TEVAR to treat ascending aortic pathologies, including dissections, aneurysms, and other disorders, the evidence 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.

POSITION STATEMENT:

Endovascular stent grafts using FDA-approved devices **meet the definition of medical necessity** for the following conditions:

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

Endovascular stent grafts are considered **experimental or investigational** for the treatment of descending aortic disorders that do not meet the above criteria, including but not limited to uncomplicated aortic dissection. The evidence is insufficient to determine the effects of the technology on health outcomes.

Endovascular stent grafts are considered **experimental or investigational** for the treatment of ascending aortic disorders, including but not limited to thoracic aortic arch aneurysms. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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 (e.g., 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 (e.g., 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 (e.g., 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 (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption); involving coverage of left subclavian artery origin, initial endoprosthesis plus descending thoracic aortic extension(s), if required, to level of celiac artery origin, radiological supervision and interpretation
75957	Endovascular repair of descending thoracic aorta (e.g., 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 (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption), radiological supervision and interpretation
75959	Placement of distal extension prosthesis(s) (delayed) after endovascular repair of descending thoracic aorta, as needed to level of celiac origin, radiological supervision and interpretation

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

Endovascular Stent Grafts for Abdominal Aortic Aneurysm, 02-33000-22

OTHER:

None Applicable

REFERENCES:

1. Biancari F, Mariscalco G, Mariani S, et al. Endovascular treatment of degenerative aneurysms involving only the descending thoracic aorta: systematic review and meta-analysis. J Endovasc Ther. Apr 2016;23(2):387-392.
2. Blue Cross Blue Shield Association Evidence Positioning System®; 7.01.86 Endovascular Stent Grafts for Disorders of the Thoracic Aorta, 09/24.
3. Boufi M, Patterson BO, et al. Endovascular Versus Open Repair for Chronic Type B Dissection Treatment: A Meta-Analysis. Ann Thorac Surg. May 2019; 107(5): 1559-1570. PMID 30481516.
4. ClinicalTrials.gov. A Randomized Controlled Comparative Study on Effectiveness of Endovascular Repair Versus Best Medical Therapy for Acute Uncomplicated Type B Aortic Dissection; accessed August 2024.
5. Elkbuli A, Dowd B, et al. Thoracic Endovascular Aortic Repair Versus Open Repair: Analysis of the National Trauma Data Bank. J Surg Res. Jan 2020; 245: 179-182. PMID 31421360.
6. Gennai S, Leone N, et al. Systematic review and meta-analysis of long-term reintervention following thoracic endovascular repair for blunt traumatic aortic injury. J Vasc Surg. 2023 Aug;78(2):540-547.e4. PMID: 36754248.
7. 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-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. May 4 2012;33(13):1558-1563.
8. 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: Executive summary: 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 Apr 6;55(14): e27-e129.
9. Isselbacher EM, Preventza O, 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 Dec 13;146 (24): e334-e482.
10. MacGillivray TE, Gleason TG, et al. The Society of Thoracic Surgeons/American Association for Thoracic Surgery clinical practice guidelines on the management of type B aortic dissection. J Thorac Cardiovasc Surg. 2022 Apr;163(4):1231-1249.
11. Makaroun MS, Dillavou ED, Kee ST, Sicard G, Chaikof E, Bavaria J, Williams D, Cambria RP, Mitchell RS. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. J Vasc Surg. 01/05; 41(1): 1-9.
12. National Institute for Clinical Excellence (NICE). A systematic review of the recent evidence for the efficacy and safety relating to the use of endovascular stent-graft (ESG) placement in the treatment of thoracic aortic disease, 2005; accessed at nice.org.
13. Sá MP, Jacquemyn X, et al. Midterm Outcomes of Endovascular vs. Medical Therapy for Uncomplicated Type B Aortic Dissection: Meta-Analysis of Reconstructed Time to Event Data. Eur J Vasc Endovasc Surg. 2023 Nov;66(5):609-619. PMID: 37422209.

14. Scalea TM, Feliciano DV, et al. Blunt Thoracic Aortic Injury: Endovascular Repair Is Now the Standard. J Am Coll Surg. Apr 2019; 228(4): 605-610. PMID 30630086.
15. U.S. Food and Drug Administration (FDA), accessed at fda.gov.
16. Upchurch GR, Escobar GA, et al. Society for Vascular Surgery clinical practice guidelines of thoracic endovascular aortic repair for descending thoracic aortic aneurysms. J Vasc Surg. 2021 Jan;73(1S):55S-83S.
17. Veith FJ, Abbott WM, et al. Endovascular Graft Committee, an Ad Hoc Conjoint Committee of the Joint Council of the Society for Vascular Surgery and International Society for Cardiovascular Surgery and Society of Interventional Radiology. Guidelines for development and use of transluminally placed endovascular prosthetic grafts in the arterial system. J Vasc Interv Radiol. 2003 Sep; 14(9 Pt 2): S405-17.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

04/15/03	New Medical Coverage Guideline.
04/15/04	Review and revision to guideline; consisting of updated references and no change to investigational status.
04/15/05	Review and revision to guideline; consisting of updated references.
05/15/05	Revision to guideline; consisting of formatting changes.
01/01/06	Annual HCPCS coding update consisting of the deletion of 0033T – 0040T and the addition of 33880 – 33891 and 75956 – 75959.
03/15/06	Review and revision of guideline consisting of updated references and addition of coverage criteria.
08/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
06/15/09	Biennial review: position statement maintained, description section and updated references.
05/15/11	Biennial review: position statement and references updated.
05/11/14	Revision: Program Exceptions section updated.
11/15/16	Revision; title, description, position statement, coding, and references updated.
08/15/18	Revision; description, position statements, and references updated.
08/15/20	Review; position statements maintained and references updated.
08/15/22	Review: Position statements maintained; references updated.
05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
10/15/24	Review: Position statements maintained, description and references updated.