Policy Statement:

I. Based upon our criteria and assessment of peer-reviewed literature, endovascular repair of abdominal aortic aneurysms (AAA) using FDA approved endoprostheses is a medically appropriate option for:
   A. Patients with aneurysms measuring 5 cm or greater in diameter;
   B. Women or small individuals, with aneurysms measuring twice the diameter of the normal aorta at the infrarenal neck;
   C. Individuals in whom an enlarging aneurysm is:
      1. symptomatic, or
      2. greater than 4 cm in diameter and has increased in size by 0.5 cm in the last 6 months.
   D. Patients with a ruptured or suspected ruptured abdominal aortic aneurysm (See Policy Guideline II).

II. Based upon our criteria and assessment of peer-reviewed literature, endovascular repair of abdominal aortic aneurysms involving visceral vessels using a fenestrated graft is considered investigational.

III. Based upon our criteria and assessment of peer-reviewed literature, endovascular repair of descending thoracic aortic aneurysms (DTAA) with a FDA-approved endoprosthesis is considered a medically appropriate option when the device is used according to FDA labeling (see Rationale section) for the following indications:
   A. An intact descending thoracic aortic aneurysm (elective repair);
   B. A ruptured descending thoracic aortic aneurysm; or
   C. An acute, complicated type B dissection of the descending thoracic aortic aneurysm.

IV. Based upon our criteria and assessment of peer-reviewed literature, endovascular repair of thoracic aortic arch aneurysms or uncomplicated (chronic) descending thoracic aortic dissections has not been medically proven to be effective and is considered investigative.

V. Based upon our criteria and assessment of peer-reviewed literature, use of wireless pressure sensors is considered investigative in the management (intra-operative and/or post-operative) of patients having endovascular aneurysm repair.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Policy Guidelines:

I. The use of 5 cm as a reference point for the diameter of an aneurysm warranting repair is based on the fact that 5 cm defines a size at which open surgical repair of an abdominal aortic aneurysm is typically considered. A diameter of 5 cm was patient selection criterion in one of the clinical trials presented to the FDA as part of the FDA approval process.

II. There are 3 major clinical factors that must be considered in treating ruptured AAAs endoluminally:
   A. the patient must be hemodynamically stable enough to undergo detailed computed tomography with anatomic measurements;
   B. the aneurysm should be anatomically suitable for EVAR; and
   C. the necessary dedicated specialized personnel should be available.
The conventional management of clinically significant abdominal or thoracic aortic aneurysms consists of surgical exposure, with or without, excision of the aneurysm (laparotomy or thoracotomy) with placement of a graft. Due to long operative times, need for cardiopulmonary bypass and a variety of peri- and postoperative complications associated with surgical management of abdominal or thoracic aortic aneurysms, endovascular prostheses have been investigated as a less invasive, catheter-based alternative to open surgical repair. The endovascular graft or stent is introduced through the femoral artery and passed up the iliac artery into the aorta, or in the case of endovascular repair of a TAA, can be passed directly into the aorta. The device is then deployed across the aneurysm such that the aneurysm is effectively “excluded” from the circulation with subsequent restoration of normal blood flow.

There are several types of AAA endovascular grafts – straight grafts, in which both ends are anchored in the infrarenal aorta, and bifurcated grafts, in which the proximal end is anchored in the infrarenal aorta and the distal ends are anchored in the iliac arteries. The use of a straight versus bifurcated graft depends on the extent of the aneurysm. Fenestrated grafts are also being investigated. Depending upon the graft manufacturer, fixation of grafts occurs by attachment hooks, barbs or radial force. Grafts that extend across the visceral arteries (fenestrated modular bifurcated prostheses) have fenestrations or scallops in the graft material that allow for the proximal edge of the graft material to be placed above the renal arteries to allow blood flow to vessels accommodated by the fenestrations. Each fenestrated graft is custom made for each patient prior to an elective surgery in order to allow for anatomical variation.

The success of endovascular stent grafts of abdominal aortic aneurysm created interest in applying the same technology to the aneurysms and dissections of the descending or thoracoabdominal aorta. In March 2005, the FDA approved the Gore TAG Endoprosthesis System for use in descending thoracic aneurysms. The system consists of an endovascular graft and a metallic support structure, and a delivery system used to implant the graft. The graft is delivered by a catheter inserted into the femoral artery in the groin.

The goal of aortic aneurysm repair is to reduce pressure in the aneurysm sac and thus prevent rupture. Failure to completely exclude the aneurysm from the systemic circulation results in continued pressurization. An endoleak (persistent perfusion of the aneurysmal sac) may be primary (within the first 30 days) or secondary (after 30 days). The completeness of exclusion or absence of endoleaks is evaluated by intraoperative angiography. Since endoleaks may also develop subsequent to the time of surgery, CT, MR, and ultrasound are used in monitoring the aneurysmal sac. Percutaneous catheter-based approaches can also be used to measure intrasac pressures postoperatively. Wireless implantable pressure-sensing devices are being evaluated to monitor pressure in the aneurysm sac. These implanted devices use various mechanisms to wirelessly transmit pressure readings to devices for measuring and recording pressure. These devices have the potential to improve outcomes for patients who have had endovascular repair. They may change the need for or frequency of monitoring of the aneurysm sac using contrast-enhanced CT scans. They may improve postoperative monitoring. However, the accuracy of these devices must be determined and potential benefits and risks must be considered and evaluated. At the present time, two types of systems are being evaluated; radiofrequency or ultrasound based systems.

RATIONALE:

Abdominal aorta

Several grafts have been FDA approved, including but not limited to, the Gore Excluder (2002), the Zenith AAA Endovascular Graft (2003 – now called Zenith Flex AAA Endovascular Graft), the Endologix Powerlink (2004), the Medtronic Talent Abdominal Stent Graft System (2008), and Medtronic Endurant AA stent graft (2010), and the Aorfix™ AAA Flexible Stent Graft System (2013, Lombard Medical, PLC)(2). In 2012, the Ovation™ Abdominal Stent Graft System (TriVascular, Inc.), a lower-profile stent graft that uses a post-implantation polymer deployment system to seal the device to the aorta, was approved for endovascular repair of abdominal aortic aneurysms with suitable anatomy.
Clinical trials have reported perioperative mortality rates for endovascular AAA repair from 0-2.7%. The endovascular AAA repair method allows for significant reductions in pulmonary and gastrointestinal complications, decreases blood loss and the need for blood replacement, and shortened hospital stays. While endoleaks, graft migration and device related complications of the grafts may require reintervention, rupture-free survival rates are similar to patients receiving open repair.

Endovascular repair has been increasingly used as an alternative to open surgical repair of ruptured abdominal aortic aneurysms (RAAAs) in patients with anatomic configuration suitable for this type of repair. The reported operative mortality in these patients compares favorably with the mortality rate of 40% to 50% that is usually reported for patients treated by open surgery. The most significant benefits from endovascular procedures for RAAAs correlate with the institution’s endovascular experience. A Cochrane systematic review (Dillon, et al., 2007) was conducted to compare advantages and disadvantages of endovascular treatment compared to open surgical repair for treatment of ruptured AAA. The authors stated that there is no high-quality evidence to support the use of endovascular repair of ruptured AAA. Results of available studies cannot be interpreted confidently because of the nature of the studies. However, evidence from prospective controlled studies, prospective studies, and retrospective case series, suggest that endovascular repair is feasible in selected patients, with outcomes comparable to best conventional open surgical repair. In selected patients, endovascular repair may be associated with a trend toward reduction in blood loss, duration of intensive care treatment, and mortality.

The Zenith® Fenestrated AAA Endovascular Graft, a graft that extends across the visceral arteries, was approved by the FDA with the adjunctive Zenith Alignment Stent in April 2012. Preliminary results of the use of a fenestrated graft in these situations suggested that the use of such a graft was technically challenging but feasible, but that more patients with greater follow-up are required to determine the long-term safety, effectiveness, and long-term outcomes of the procedure.

Thoracic aorta

On March 23, 2005 the FDA approved the GORE TAG Endoprosthesis System for use in descending thoracic aneurysms. The GORE TAG Thoracic Endoprosthesis device is approved for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy, including: adequate iliac/femoral access; aortic inner diameter in the range of 23-37 mm; and greater than or equal to 2 cm non-aneurysmal aorta proximal and distal to the aneurysm. Similar to the FDA approval of abdominal aortic stent grafts, the FDA approved the system based on review of two nonrandomized clinical studies (PIVOTAL TAG 99-01 and TAG 03-03) of the system’s safety and effectiveness. These studies involved approximately 200 people. Study results showed that aneurysm-related deaths were lower in patients who had received the endoprosthesis than in the surgical control group. A prospective controlled multicenter study (Makaroun, et al., 2005) provided additional information on the 142 patients from the TAG 99-01 trial. The study reported favorable aneurysm-related (97%) and overall survival (75%) rates and concluded the GORE TAG device was a safe alternative treatment for descending aortic aneurysm. In January 2012, the FDA granted an expanded 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 16-42 mm, with >20mm of non-aneurysmal aortic distal and proximal to the lesion.

Zenith® TX2® Thoracic TAA Endovascular graft with the H & L-B One-Shot Introduction System (Cook) received FDA approval in May 2008. It is indicated for the endovascular treatment with aneurysms 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; non-aneurysmal aortic segments (fixation sites) proximal and distal to the aneurysm or ulcer with a length of at least 25 mm and with a diameter measured outer wall to outer wall of no greater than 38 mm and no less than 24 mm. The STARZ-TX2 Clinical Trial is a non-randomized, controlled, multi-center, study (n = 230) that was conducted to evaluate safety and effectiveness of the Zenith TX2® TAA Endovascular Graft in the elective treatment of patients with descending thoracic aortic aneurysms or ulcers, as compared to open surgical repair. The one-year results (Matsumura, et al. 2008) are as follows: The 30-day survival rate was noninferior (P less than .01) for the thoracic endovascular aortic repair (TEVAR) group compared with the open group (98.1% vs. 94.3%). The
severe morbidity composite index was lower for TEVAR (0.2 +/- 0.7 vs. 0.7 +/- 1.2; P less than .01). Cumulative major morbidity scores were significantly lower at 30 days for the TEVAR group compared with the open group (1.3 +/- 3.0 vs. 2.9 +/- 3.6, P less than .01). The TEVAR patients had fewer cardiovascular, pulmonary, and vascular adverse events, although neurologic events were not significantly different. Clinical utility for the TEVAR patients was superior to that of the open patients. No ruptures or conversions occurred in the first year. Reintervention rates were similar in both groups. At 12 months, aneurysm growth was identified in 7.1% (8/112), endoleak in 3.9% (4/103), migration (greater than 10 mm) in 2.8% (3/107), and other device issues were rare. None of the patients with migration experienced endoleak, aneurysm growth, or required a secondary intervention.

The VALOR Pivotal Study (VALOR Test Group) was a multi-center, non-randomized clinical study conducted within the U.S. to evaluate the safety and effectiveness of the Talent™ Thoracic Stent Graft System when used in the treatment of subjects with descending thoracic aortic aneurysms (fusiform aneurysms and saccular aneurysms/penetrating ulcers). Endovascular results were compared with open surgical data from three centers of excellence. A total of 157 patients out of the 195 enrolled were available for 12-month follow-up. VALOR results (Fairman, et al. 2008) included all-cause mortality, 16.1%; aneurysm-related mortality, 3.1%; conversion to open surgery, 0.5%; target aneurysm rupture, 0.5%; stent graft migration greater than 10 mm, 3.9%; endoleak (12.2%), stent graft patency, 100%; stable or decreasing aneurysm diameter, 91.5%; and loss of stent graft integrity, four patients. No deployment-related events or perforation of the aorta by a graft component occurred. The Talent Thoracic Stent Graft showed statistically superior performance with respect to acute procedural outcomes (P less than .001), 30-day major adverse events (41% vs. 84.4%, P less than .001), perioperative mortality (2% vs. 8%, P less than .01), and 12-month aneurysm-related mortality (3.1% vs. 11.6%, P less than .002) vs. open surgery.

In October 2012, the FDA granted approval for the Valiant™ Thoracic Stent Graft with the Captivia Delivery System (Medtronic Vascular, Santa Rosa, CA) 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 diameter is 18-42 for aneurysms and penetrating ulcers, and 18-44 mm for blunt traumatic injuries.

Overall, the evidence is sufficient to determine that the use of endovascular stent grafts in the thoracic aorta are associated with equivalent or improved outcomes compared to open surgical repair and are a reasonable alternative for patients who meet specific anatomic criteria.

Endovascular stenting is being evaluated as an alternative treatment to surgical or medical therapy for thoracic aortic aneurysms, acute and chronic dissections, and traumatic aortic tears or ruptures. There are no randomized trials of stenting versus alternative treatments to provide high-quality evidence of the efficacy of one approach over another for aneurysms or acute dissections or tears (traumatic injury). Compared to elective endovascular repair of thoracic aneurysms the data for complex situations are more limited. The evidence on TEVAR for treatment of thoracic artery rupture consists of single-arm series and nonrandomized comparative studies. There are no randomized, controlled trials, but RCTs are likely difficult to complete for this indication because of the emergent nature. The available evidence suggests that early mortality and complications are less with TEVAR compared with open surgery, but these data are limited by non-comparability of groups. The longer-term outcomes are uncertain, with no discernible differences between TEVAR and open surgery.

Both short- and intermediate-term results from a number of series for complicated (organ or limb ischemia or rupture) type B dissection suggest a benefit for use of TEVAR. There was strong clinical support for this use of TEVAR. For uncomplicated descending (type B) aortic dissections, the evidence available from one randomized trial does not suggest that stent grafts have superior outcomes compared to medical therapy. Therefore, the impact on net health outcome is not known.

Wireless pressure monitoring

In October 2006, the FDA cleared the CardioMEMS EndoSure™ (radiofrequency-based) system through the 510(k) process. The favorable FDA review indicated only that the device was substantially equivalent to legally marketed predicate devices. The FDA labeling indications noted that the device is intended for measuring intrasac pressure during
endovascular abdominal aortic aneurysm repair. It also noted that it might be used as an adjunctive tool in the detection of intraoperative endoleaks. The ImPressure™ system (ultrasound-based) is in use in Europe and is being used as part of an investigation device exemption (IDE) trial of stent grafts.

There is currently insufficient data to indicate if use of this device improves clinical outcomes. The accuracy of the device in those with various types of endoleaks needs to be determined with larger numbers of patients. Also, the performance over time needs to be addressed. Work is also needed to determine the type and number of devices that might best be used in monitoring. That is, because of sac compartmentalization a pressure-sensing device might not detect an endoleak. It also is not known if there might be important long-term complications from this implanted device. Thus, at this time until important questions are addressed, this device is considered investigational.

**CODES:**

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<td>Radiologic supervision and interpretation associated with endovascular repair of thoracic aneurysm (code range)</td>
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**HCPCS:** No specific codes

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REFERENCES:


*BlueCross BlueShield Association Technology Evaluation Center (TEC). Endovascular stent-grafts for abdominal aortic aneurysm repair. 2001 May;16(2).

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SUBJECT: ENDOVASCULAR GRAFTS FOR ABDOMINAL AND THORACIC AORTIC ANEURYSMS

POLICY NUMBER: 7.01.33
CATEGORY: Technology Assessment

EFFECTIVE DATE: 05/18/00
REVISED DATE: 09/01/01, 09/19/02, 07/17/03, 05/19/04, 05/18/05, 05/18/06, 05/17/07, 06/19/08, 05/28/09, 04/22/10, 03/17/11, 05/24/12, 04/18/13, 05/22/14


Investigators IT. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomized trial. BMJ 2014 Jan 13;348:f7661.


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*key article

**KEY WORDS:**

Abdominal aortic aneurysm, CardioMEMS EndoSure, Endograft, Endoprosthesis, Endovascular graft, Thoracic aortic aneurysm.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, endovascular grafts for the repair of abdominal and thoracic aortic aneurysms are not specifically addressed in National or Regional Medicare coverage determinations or policies.