Endovascular Repair of Aortic Aneurysms

Number: 0651

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

I. Aetna considers endovascular repair of infra-renal abdominal aortic or aorto-iliac aneurysms with a Food and Drug Administration (FDA)-approved nonfenestrated endovascular stent graft medically necessary.

II. Aetna considers endovascular repair of abdominal aortic aneurysms involving visceral blood vessels using a fenestrated modular bifurcated prosthesis experimental and investigational because there are insufficient data on the long-term safety and effectiveness of this device.

III. Aetna considers endovascular repair of descending thoracic aortic aneurysms with a FDA-approved endoprosthesis medically necessary.

IV. Aetna considers placement of visceral extension prosthesis for endovascular repair of abdominal aortic aneurysm involving visceral vessels experimental and investigational because its effectiveness has not been established.

Policy History

Last Review 07/28/2016
Effective: 01/17/2003
Next Review: 07/27/2017

Definitions

Additional Information

Clinical Policy Bulletin Notes
V. Aetna considers implanted wireless pressure sensors for detection of endoleaks in the aneurysmal sac following endovascular repair experimental and investigational because of inadequate published evidence of their clinical effectiveness.

VI. Aetna considers fabric/mesh wrapping of abdominal aortic aneurysms experimental and investigational because its effectiveness has not been established.

VII. Aetna considers CT surveillance after endovascular (stent) aortic repair at 1 month, 6 months, and 12 months following repair, then every year medically necessary.

VIII. Aetna considers the use of multi-branched stent-grafts in the treatment juxta-renal abdominal, para-renal abdominal, and thoraco-abdominal aortic aneurysms experimental and investigational because its effectiveness of this approach has not been established.

Background
Aortic aneurysms can develop anywhere along the length of the aorta, but 3/4 are located in the abdominal aorta. Thoracic aortic aneurysms, including those that extend from the descending thoracic aorta into the upper abdomen (thoraco-abdominal aneurysms), account for 1/4 of aortic aneurysms.

Abdominal aortic aneurysms (AAAs) are the most common form of aortic aneurysm, and are a potentially life-threatening condition. It is estimated 1 to 4% of persons over age 50 years are affected (O'Connor, 2002). Rupture of an AAA is the 13th most common cause of death in the United States.

Abdominal aortic aneurysm is usually the result of degeneration in the media of the arterial wall, resulting in a slow and continuous dilatation of the lumen of the vessel. In fewer than 5% of cases, AAA is caused by mycotic aneurysm of hematogenous origin. Abdominal aortic aneurysms are usually asymptomatic until they expand or rupture. Presence of a
pulsatile abdominal mass is virtually diagnostic but is found in less than 50% of cases. Rupture is uncommon if aneurysms are less than 5 cm in diameter, but ruptures are dramatically more common for aneurysms greater than 6 cm in diameter. Without prompt intervention, ruptured aneurysms are often fatal. Thus, elective surgical repair is usually recommended for all aneurysms greater than 6 cm unless surgery is contraindicated (Beers et al, 1999). In patients who are good surgical risks, elective repair is generally recommended for aneurysms between 5 and 6 cm (mortality, about 2 to 5%).

For an AAA, the standard open approach to repair involves a long midline abdominal incision, and placement of a graft in the aneurismatic sac. It is now possible to secure a bifurcated graft within an aneurysm at the latter site using a femoral approach from within the vessel. The use of an endovascular graft may be considered when the risks of an open repair of the aneurysm are unacceptable, and the risk of aneurysm rupture is high, as indicated by any of the following criteria: (i) diameter of aneurysm is greater than 5 cm; or (ii) diameter of aneurysm is 4 to 5 cm and has increased in size by 0.5 cm in the past 6 months; or (iii) diameter of aneurysm is twice the diameter of the normal infrarenal aorta.

Current endovascular graft stents require an infra-renal non-aneurysmal neck length of at least 15 mm; however, there are case reports that describe the use of a fenestrated stent graft (Zenith, Cook, Inc., Bloomington, IN) customized to meet the anatomic needs of the individual patient. The Zenith fenestrated graft, which is not FDA-approved, is based on Cook's FDA-approved Zenith AAA endovascular graft design. It incorporates scallops at the top and openings in the graft wall called fenestrations that allow it to be implanted precisely in the aorta across adjacent blood vessels without blocking blood flow through those vessels. Accurate placement of a fenestration over the orifice of a target vessel is feasible, but long-term maintenance of position is dependent on secure graft fixation (Stanley, 2001).
Verhoeven et al (2004) used a customized fenestrated graft based on the Cook Zenith composite system on 18 patients who had the following criteria: abdominal aneurysm at least 55 mm in diameter, a short neck (less than 15 mm), and contraindications for open repair (cardiopulmonary impairment or a hostile abdomen). Additional stents were used to ensure apposition of the fenestrations with the side branches. Of the 46 targeted side branches, 45 were patent at the end of the procedure. At follow-up (mean of 9.4 months), all of the remaining targeted vessels stayed patent. The authors concluded that by customizing fenestrated stent-grafts, it is possible to position the first covered stent completely inside the proximal neck, thus achieving a more stable position. This technique may become a valuable alternative for patients with a short infrarenal non-aneurysmal neck length; however, more patients with longer follow-up are required to determine the long-term safety and effectiveness of the device.

Verhoeven and colleagues (2009) noted that recent developments with fenestrated and branched stent grafts have opened the way to treat complex aortic aneurysms involving the visceral arteries. Early reports on endovascular treatment of thoraco-abdominal aneurysms have demonstrated the feasibility of the technique. Given the sparse literature, its safety has not been established yet. These researchers performed a literature review and also presented the results of their own series of 30 patients treated with a custom-made Zenith device with fixed branches are presented. Most of the patients were refused open surgery mainly for the extent of the disease combined with co-morbidity, which included in most patients a combination of several risk factors. The mean aneurysm size was 70 mm and the extent of the aneurysm was type I in 8 cases, type II in 5, type III in 12 and type IV in 5 patients. Technical success in the authors’ series was achieved in 93 % (28/30). Two out of 97 (2 %) targeted vessels were lost. In 1 patient, a renal artery ruptured during insertion of the bridging stent graft. In a second patient, a celiac artery could not be catheterized and was lost. The 30-day mortality was 6.7 % and corroborated with 5.5 % in the largest series reported so
The 6-month and 1-year survival were 89.3 % and 76.0 %, respectively. The authors concluded that the results of fully endovascular repair of selected thoraco-abdominal aneurysms are promising. A learning curve should be expected. Anatomical limitations such as extremely tortuous vessels and access problems should be taken into account, as well as the quality of the targeted side branches. Although longer-term results need to be awaited, it is likely that endovascular repair of thoraco-abdominal aneurysms will become a preferential treatment option for many patients in the future.

Monahan and Schneider (2009) stated that open surgical repair of complex aortic aneurysms, such as juxtarenal or thoraco-abdominal aortic aneurysms, is a highly demanding procedure. They frequently require major surgical exposure through both the thoracic and the abdominal cavities, supra-renal or supracleiac aortic cross-clamping, and exposure of the visceral and renal arteries. Endovascular aortic repair and thoracic endovascular aortic repair have become the mainstay of treatment for infra-renal AAAs and descending thoracic aneurysms. However, the obvious need to maintain perfusion of the visceral and renal arteries has limited application of endovascular techniques to treatment of more complex aneurysms. Fenestrated and branched stent grafts are being developed to address this need and enable repair of complex aneurysms involving branch vessels exclusively using minimally invasive techniques. Although these devices remain investigational in the United States, they have recently become commercially available in other countries and play an increasing role in the management of complex aortic aneurysms.

Amiot and associates (2010) evaluated the medium-term outcomes following aortic aneurysm repair using fenestrated endografts performed in 16 French academic centers. A retrospective analysis of prospectively collected data was carried out. This study included all patients treated with fenestrated endografts in France between May 2004 and January 2009. Patients were judged to be at high-risk for open surgical repair. Fenestrated endografts were designed using
computed tomography (CT) reconstructions performed on 3-
dimensional work-stations. All patients were evaluated with
CT, duplex ultrasound and plain film radiograph at discharge, 6,
12, 18 and 24 months, and annually thereafter. A total of 134
patients (129 males) were treated over the study period.
Median age and aneurysm size were 73 years (range of 48 to 91
years) and 56 mm (range of 45 to 91 mm), respectively. A total
of 403 visceral vessels were perfused through a fabric
fenestration, including 265 renal arteries. One early conversion
to open surgery was required. Completion angiography and
discharge CT scan showed that 398/403 (99%) and 389/394 (99
%) respective target vessels were patent. The 30-day mortality
rate was 2% (3/134). Pre-discharge imaging identified 16 (12
%) endoleaks: 3 type I, 12 type II and 1 type III. After the
procedure, transient or permanent dialysis was required in 4 (3
%) and 2 (1%) patients, respectively. The median duration of
follow-up was 15 months (range of 2 to 53 months). No
aneurysms ruptured or required open conversion during the
follow-up period. Twelve of 131 patients (9%) died during
follow-up (actuarial survival at 12 and 24 months: 93% and 86
%, respectively). Median time from procedure to death was 15
months. None of these deaths were aneurysm related.
Aneurysm sac size decreased by more than 5 mm in 52 %, 65.6
% and 75 % of patients at 1, 2 and 3 years, respectively. Three
(4 %) patients had sac enlargement within the 1st year,
associated with a persistent endoleak. During follow-up, 4
renal artery occlusions were detected. A total of 12 procedure-
related re-interventions were performed in 12 patients during
follow-up, including 6 to correct endoleaks, and 5 to correct
threatened visceral vessels. The authors concluded that the use
of endovascular prostheses with graft material incorporating
the visceral arteries is safe and effective in preventing rupture
in the medium-term. A predictable high mortality rate was
depicted during follow-up in this high-risk cohort. Meticulous
follow-up to assess sac behaviour and visceral ostia is critical to
ensure optimal results.

An evidence report from the Agency for Healthcare Research
and Quality (Wilt et al, 2006) on treatment options to repair
AAA found that more research is needed to evaluate the long-term benefits and harms of endovascular repair versus open surgical repair. According to this report, in patients medically fit for surgery and with an AAA of 5.5 cm or more, endovascular repair is a less invasive procedure, requires a shorter length of stay, and is associated with lower 30-day morbidity and mortality that open surgical repair. However, studies have not shown improved quality of life beyond 3 months or survival beyond 2 years, according to the report. Endovascular repair is associated with more complications, increase need for re-intervention, more long-term radiological monitoring, and greater costs when compared with open surgical repair. A 4-year study of 166 endovascular repair patients medically unfit for surgery found that endovascular repair did not confer any survival benefit compared with no intervention. The authors concluded that research is needed to evaluate the cost-effectiveness of endovascular repair in the United States (Wilt et al, 2006). Research is also needed to evaluate whether the outcomes of endovascular repair procedures are influenced by either hospital volume or the surgeon's experience.

Lee and Faries (2007) noted that the increasing use of endografts to treat AAA has prompted the need for improved post-operative imaging and surveillance. Although patients benefit from decreased morbidity with endovascular repair compared with open AAA repair, the long-term outcome of stent repair has yet to be fully determined.

Jonk et al (2007) performed a systematic review of the cost-effectiveness of AAA repair. Of the 20 eligible articles, there were 3 randomized controlled trials (RCTs), 12 case series, 4 Markov models, and 1 systematic review. Regardless of time frame, all studies found that endovascular repair costs more than open surgery. Although the high cost of the endovascular prosthesis was partially offset by reduced intensive care, hospital length of stay, operating time, blood transfusions, and peri-operative complications, hospital costs were still greater for endovascular than open surgical repair. For patients
medically fit for open surgery, mid-term costs were greater for endovascular repair with no difference in overall survival or quality of life. For patients medically unfit for open surgery, endovascular repair costs more than no intervention with no difference in survival. The authors stated that although conclusions regarding the cost-effectiveness of AAA treatment options are time dependent and vary by institutional perspective, from a societal perspective, endovascular repair is not currently cost-effective for patients with large AAA regardless of medical fitness.

On the other hand, Brewster and colleagues (2006) reviewed a 12-year experience with endovascular AAA repair (EVAR) to document late outcomes. During the interval between January 7, 1994 and December 31, 2005, a total of 873 patients underwent EVAR utilizing 10 different stent graft devices. Primary outcomes examined included operative mortality, aneurysm rupture, aneurysm-related mortality, open surgical conversion, and late survival rates. The incidence of endoleak, migration, aneurysm enlargement, and graft patency was also determined. Finally, the need for re-intervention and success of such secondary procedures were evaluated. Kaplan-Meier and multi-variate methodology were used for analysis. Mean patient age was 75.7 years (range of 49 to 99 years); 81.4% were male. Mean follow-up was 27 months; 39.3% of patients had 2 or more major co-morbidities, and 19.5% would be categorized as unfit for open repair. On an intent-to-treat basis, device deployment was successful in 99.3%. Thirty-day mortality was 1.8%. By Kaplan-Meier analysis, freedom from AAA rupture was 97.6% at 5 years and 94% at 9 years. Significant risk factors for late AAA rupture included female gender (odds ratio OR, 6.9; p = 0.004) and device-related endoleak (OR, 16.06; p = 0.009). Aneurysm-related death was avoided in 96.1% of patients, with the need for any re-intervention (OR, 5.7; p = 0.006), family history of aneurysmal disease (OR, 9.5; p = 0.075), and renal insufficiency (OR, 7.1; p = 0.003) among its most important predictors. A total of 87 (10%) patients required re-intervention, with 92% of such procedures being catheter-based and a success rate of
84 %. Significant predictors of re-intervention included use of first-generation devices (OR, 1.2; p < 0.01) and late onset endoleak (OR, 64; p < 0.001). Current generation stent grafts correlated with significantly improved outcomes. Cumulative freedom from conversion to open repair was 93.3 % at 5 through 9 years, with the need for prior re-intervention (OR, 16.7; p = 0.001) its most important predictor. Cumulative survival was 52 % at 5 years. The authors concluded that EVAR using contemporary devices is a safe, effective, and durable method to prevent AAA rupture and aneurysm-related death. Assuming suitable AAA anatomy, these data justify a broad application of EVAR across a wide spectrum of patients.

Frank et al (2007) performed a systematic review and meta-analysis of 12 years of EVAR. A total of 163 studies pertaining to 28,862 patients undergoing EVAR were identified as relevant for the review and meta-analysis. The pooled estimate for operative mortality was 3.3 % (95 % confidence interval [CI]: 2.9 to 3.6 %). The pooled estimate for type 1 endoleaks was 10.5 % (95 % CI: 9.0 to 12.1 %), with an annual rate of 8.4 % (95 % CI: 5.7 to 12.2 %). The pooled estimate of type 2,3 and 4 endoleaks was 13.7 % (95 % CI: 12.3 to 15.3 %), with an annual rate of 10.2 % (95 % CI: 7.4 to 14.1 %). The pooled estimate for primary conversion to open repair was 3.8 % (95 % CI: 3.2 to 4.4 %), and for secondary conversion to open repair 3.4 % (95 % CI: 2.8 to 4.2 %). The pooled estimate for post-operative rupture was 1.3 % (95 % CI: 1.1 to 1.7 %), with an annual rupture rate of 0.6 % (95 % CI: 0.5 to 0.8 %). Multivariate meta-regression analysis showed that rates of operative mortality, post-operative rupture and total number of endoleaks all fell significantly (p < 0.05) over time. The authors concluded that this study demonstrated a low mortality and a gradual reduction in vascular morbidity and mortality associated with EVAR since it was first introduced.

In a systematic review, Lederle et al (2007) compared the effectiveness of treatment options, including active surveillance, open repair, and endovascular repair, for unruptured AAAs. Randomized trials that compared open or
endovascular AAA repair with another treatment strategy and published clinical outcomes were included. Two trials compared open repair with surveillance for small AAAs (n = 2,226). Repair did not improve all-cause mortality (relative risk, 1.01 [95% CI: 0.77 to 1.32]) or AAA-related mortality (relative risk, 0.78 [CI: 0.56 to 1.10]). Four trials compared open repair with endovascular repair (n = 1,532). Endovascular repair reduced 30-day mortality (relative risk, 0.33 [CI: 0.17 to 0.64]) but not mid-term (up to 4 years) mortality (relative risk, 0.95 [CI: 0.76 to 1.19]). One trial compared endovascular repair with observation in 338 patients who were unfit for open repair. Endovascular repair did not reduce all-cause mortality or AAA-related mortality, but high cross-over and procedural mortality rates complicate interpretation of results. The authors concluded that repairing AAAs smaller than 5.5 cm has not been shown to improve survival. Endovascular repair is associated with lower operative mortality than open repair, similar mid-term mortality, and unknown long-term mortality and has not been shown to improve survival in patients unfit for open repair. They stated that long-term trial data comparing endovascular repair with open repair are needed, as is another trial comparing endovascular repair with observation in high-risk patients.

Thoracic aortic aneurysms (TAAs) may be idiopathic and have been associated with congenital connective tissue disorders (e.g., Ehlers-Danlos syndrome, Marfan's syndrome). Tertiary syphilis is an uncommon cause of aneurysms. Thoracic aneurysms may become huge while remaining asymptomatic. Symptoms relate to pressure against or erosion of adjacent structures by the enlarging aorta, such as pain, cough, wheezing, hemoptysis, dysphagia, or hoarseness. Thoracic aneurysms generally should be resected if greater than or equal to 6 cm (Beers et al, 1999). However, aneurysms in patients with Marfan's syndrome are prone to rupture, so elective surgical repair is recommended for aneurysms 5 to 6 cm. Surgical repair consists of resection of the aneurysm and replacement with a synthetic conduit. Some surgeons use a homograft of the proximal aorta and aortic valve instead of
synthetic materials.

Following diagnosis, untreated patients with TAAs have a 2-year survival rate of less than 30\%, with 50\% of all deaths caused by aneurysm rupture. Complications of conventional repair include post-operative paraplegia (25\%), renal failure (20\%), bleeding, stroke, and prolonged ventilator dependence. In addition, the operative mortality of the open procedure has been reported to be about 10\%.

Endovascular repair of TAAs is one of the most recent technological advancements in vascular surgery. The current technique and available technology allow the repair of TAAs distal to the left subclavian artery (Najibi et al, 2002). This less-invasive approach has the potential to reduce the morbidity and mortality associated with the traditional open operative repair of TAAs. In addition, high-risk patients who would not be considered for open repair and would not be treated may now be candidates for this minimally invasive procedure.

The GORE TAG Thoracic Endoprosthesis System (W.L. Gore and Associates, Inc., Flagstaff, AZ) received pre-market approval (PMA) from the FDA for endovascular repair of descending TAAs in patients with the following criteria: (i) adequate iliac/femoral access; (ii) aortic inner diameter in the range of 23 mm to 27 mm; and (iii) less than or equal to 2 cm non-aneurysmal aorta proximal and distal to the aneurysm. The graft is made of expanded polytetrafluoroethylene (ePTFE) with an outer self-expanding nitinol support structure and is inserted into the diseased area of the aorta through a catheter inserted in the groin.

Gore's non-randomized pivotal study compared TAG (n = 140) with open surgery (n = 94) in 17 U.S. sites. The control group included patients who already had undergone open-surgical repair of aneurysms in the thoracic aorta (n = 50) as well as concurrent patients (n = 44), some of whose aneurysm neck length made them unsuitable for the device cohort, and some
of whom were TAG-eligible. Gore conducted a confirmatory study (n = 51) after the graft was re-designed to avoid fracture. Study results reported the TAG group was associated with reduced aneurysm-related deaths compared to the surgical group. The proportion of subjects who experienced at least 1 major adverse event (e.g., bleeding, hematoma, renal failure) through 1 year post-treatment was 42 % for the TAG group versus 77 % for the control. One major adverse event was reported between months 12 and 24. In the confirmatory study, the proportion of subjects who experienced at least 1 major adverse event was 12 % of the 51 TAG patients versus 70 % of the control. No deaths were reported for the TAG group during the first 30 days compared with 6 % of the surgical control. In addition, Gore reported that the median stay in intensive care was 1 day for the TAG group versus 3 for the control group and median length of hospital stay was 3 days for TAG versus 10 for surgery patients. The TAG group also experienced less median blood loss and returned to normal daily activities sooner.

The Interventional Procedures Advisory Committee of the National Institute for Clinical Excellence (NICE, 2005) is examining endovascular stent-graft placement in TAAs. Provisional recommendations from the Committee state that it is a suitable alternative to surgery in properly selected patients; however, the Committee emphasizes that these recommendations are provisional and subject to change. A formal guidance on the use of the procedure is expected later this year (2005).

A systematic review of the published evidence on this procedure that was commissioned by NICE (2004) identified a total of 29 studies of endovascular stent-grafting for TAAs: 27 case series and 2 comparative observational studies. In 1 comparative study, the technical success rate was 100 % (67/67 patients). The systematic review reported that the overall technical success rate was 93 % over 18 studies (16 case series and 2 comparative studies).
The systematic review reported that the rate of conversion to open repair varied from 0 % (0/26 patients) to 7 % (1/14 patients). The proportion of patients who experienced an increase in aneurysm size varied from 0 % (0/18) to 7 % (2/29) of patients. In the study with the largest number of patients, the aneurysm increased in size (by = 5 mm) in 5 % (4/84) of patients. The proportion of patients who experienced a decrease in aneurysm size varied from 100 % of patients (18/18) to 17 % (5/29) of patients. The 30-day mortality rate varied from 0 % (in several studies with a combined population of 94 patients) to 14 % (2/14) of patients. The overall mortality ranged from 3 % (1/37 patients) to 24 % (11/46 patients) across 17 studies over a mean follow-up of 14 months.

The most commonly reported complication following TAA stent-graft placement was endoleak (incomplete sealing of the aneurysm). Nineteen studies reported at least 1 patient with an endoleak, with a mean incidence of 13 % over 12 months (the total number of patients in these studies was 752; follow-up ranged from 3 to 25 months). Five studies with a total of 83 patients reported that there were no cases of endoleak during a mean follow-up period of 12 months.

Injuries to the access artery were reported in 9 case series, and included iliac artery dissection in 4 % (1/26 patients), perforation of the iliac artery in 4 % (1/27 patients) and dissection/rupture of the femoral artery in 6 % (2/34 patients). One case series reported stent fracture in 13 % (11/84) of patients, and 6 cases of stent migration were reported over 15 case series. Other reported complications included wound complications in 25 % (8/32) of patients, stroke in 19 % (8/43), renal failure requiring dialysis in 11 % (2/19), and paraplegia in 7 % (3/43) of patients. The NICE Interventional Procedure Advisory Committee noted that there is a lack of long-term data on the durability of TAA stent-grafts.

Gore is conducting a post-approval study to evaluate all-cause mortality, aneurysm-related mortality, morbidity and device-related adverse events at 30 days and 1 year post-procedure. Another condition of approval is the completion of a 2-day
training program as a prerequisite for ordering TAG.

Other endoprosthesis for TAAs under clinical investigation in the United States include the Talent (Medtronic Inc., Sunrise, FL), Valiant with the Xcelerant delivery system (Medtronic Inc., Sunrise, FL), and Zenith TX2 (Cook, Inc., Bloomington, IN).

Surgically repaired abdominal aortic aneurysms have a risk of rupture due to leakage around the graft. Patients are periodically monitored with contrast enhanced computed tomography (CT) after stent graft placement for endoleak and sac dilation which indicate increased risk of rupture.

In order to reduce the risks of rupture, endosensors are being developed to monitor abdominal aortic aneurysm pressure after endovascular repair. One manufacturer is developing a wireless radiofrequency endosensor (e.g., CardioMEMS Endosensor, CardioMEMS, Inc., Atlanta, GA). Once implanted into the aneurysm, the endosensor measures the pressure inside the sac. The pressure measurements transmitted via radiofrequency to a device held over the patient's body, where pressure readings are recorded. The device may reduce the necessary frequency of periodic monitoring of the aneurysmal sac with contrast-enhanced CT. Clinical studies of the CardioMEMS Endosensor are currently ongoing.

Another endosensor, the Impression AAA Sac Pressure Transducer, is being developed by Remon Medical, and consists of a piezoelectric membrane, which when actuated by ultrasound waves from a hand-held probe charges a capacitor. Once charged, the transducer measures ambient pressure, then generates an ultrasound signal, which is relayed to the probe. The data can then be down-loaded and exported as an Excel data file consisting of pressure measurements and the corresponding times at which the measurements were taken.

Ellozy et al (2004) reported on the first clinical experience with the use of the Impression permanently implantable, ultrasound-activated remote pressure transducer to measure
intra-sac pressure after endovascular repair of abdominal aortic aneurysms. Over 7 months, 14 patients underwent endovascular repair of an infra-renal AAA with implantation of the remote pressure transducer fixed to the outside of the stent graft and exposed to the excluded aortic sac. Twelve patients received modular bifurcated stent grafts, and 2 patients received aorto-uniiliac devices. Intra-sac pressures were measured directly with an intravascular catheter and by the remote sensor at stent-graft deployment. Follow-up sac pressures were measured with a remote sensor and correlated with systemic arterial pressure at each follow-up visit. Mean follow-up was 2.6 +/- 1.9 months. The investigators reported “excellent” concordance between catheter-derived and transducer-derived intra-sac pressure intra-operatively, with a Pearson correlation coefficient for systolic, diastolic, and pulse pressures of 0.97, 0.97, and 0.96, respectively (p < 0.001). Pulsatile waveforms were seen in all functioning transducers at each evaluation interval. One implant ceased to function at 2 months of follow-up. In 1 patient a type I endoleak was diagnosed on 1-month CT scans; 3 type II endoleaks were observed. The investigators reported that those patients with complete exclusion of the aneurysm on CT scans had a significant difference in systemic and sac systolic pressures initially (p < 0.001) and at 1 month (p < 0.001). Initial sac diastolic pressures were higher than systemic diastolic pressures (p < 0.001). The investigators reported that the ratio of systemic to sac systolic pressure increased over time in those patients with complete aneurysm exclusion (p < 0.001). Four of 6 patients with no endoleak and greater than 1-month follow-up had diminution of sac systolic pressure to 40 mm Hg or less by 3 months. The investigators concluded that additional clinical follow-up will be necessary to determine whether aneurysm sac pressure monitoring can replace CT in the long-term surveillance of patients after endovascular repair of aortic aneurysms.

Ohki et al (2007) stated that complete exclusion and de-pressurization of the aneurysm sac is the prime goal of EVAR of AAAs. Thus, any EVAR that results in a type I or III endoleak
has been classified as a technical failure. The current method to detect endoleaks uses intra-operative aortography. However, aortography is limited by its subjective nature, inability to quantify the significance of the endoleak, and artifacts such as bowel gas that may mimic an endoleak. In addition, repetitive contrast injection may impair renal function. To increase the safety and effectiveness of intra-operative endoleak detection, a wireless pressure-monitoring system has been developed and tested in the clinical setting. The APEX trial (Acute Pressure Measurement to Confirm Aneurysm Sac EXclusion) is a prospective, multi-center/international trial sponsored by CardioMEMS to evaluate the safety and effectiveness of the EndoSure wireless pressure sensor for EVAR. The 30 x 5 x 1.5-mm sensor contains no battery and is powered externally with radiofrequency energy. The sensors are extremely stable, operate over the full physiological range of pressures, and have a resolution of 1 mm Hg. A total of 90 patients were enrolled at 12 sites, 76 of whom were eligible for analysis. The sensor was implanted via the contralateral femoral artery at the time of EVAR. The sac pulse pressure was measured with both an angiographical catheter and the sensor after deployment of the main endograft but before the deployment of the contralateral limb (type I endoleak equivalent). Sac pressure was again measured with the sensor after deployment of the contralateral limb and completion of the EVAR. Data were collected in a prospective manner. In all of the eligible patients (n = 76), the initial sensor pressure measurement agreed closely with the angiographical catheter pressure measurement of the type I endoleak equivalent. At the completion of the procedure, there was agreement between the sensor measurement and angiography regarding the presence or absence of a type I or III endoleak in 92.1% (n = 70) of the measurements. Overall, the sensitivity was 0.94 and the specificity was 0.80 for detecting type I or III endoleaks. Final pulse pressures decreased significantly compared with baseline measurements. The authors concluded that implantation of the wireless pressure sensor is safe, and remote aneurysm sac pressure sensing is feasible. It was a valuable guide in evaluating the completeness of the
EVAR procedure. Moreover, they stated that long-term study will be needed to prove its effectiveness for post-operative surveillance.

Fabric wrapping for abdominal aortic aneurysms entails wrapping aneurysms with cellophane or fascia lata. Karkos et al (2002) stated that “whether external wrapping does alter the outcome in patients with unresected AAAs and a gain in longevity for the individual can be achieved is unclear .... the question whether one could justify employing this old-fashioned technique, as a last resort, to delay rupture in selected poor-risk patients unfit for open repair, with large aneurysms that extend above the renal arteries and those unsuitable for endovascular surgery remains unanswered”.

Fabric wrapping for abdominal aortic aneurysms has not been demonstrated to prevent eventual rupture. In extremely rare instances, external wall reinforcement may be indicated when the current accepted treatment (excision of the aneurysm and reconstruction with synthetic materials) is not a viable alternative, but external wall reinforcement is not fabric wrapping. It should also be noted that of fabric wrapping of abdominal aortic aneurysms is not covered by Medicare (2001).

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2009) concluded that endovascular aortic stent-grafts are not recommended for patients with ruptured aneurysms except in the context of research.

Foster et al (2010) examined whether a policy for endovascular repair as the primary mode of treatment for ruptured abdominal aortic aneurysms (rAAAs) would improve outcomes. A total of 1,328 papers were found; of these, 24 presented represent the best evidence to answer the clinical question.

The author, journal, date and country of publication, patient group studies, study type, relevant outcomes, results, and study weaknesses of these papers were tabulated. The majority of data available derives from level 2b evidence, with only 1 single level 1b and no level 1a studies available. Appraisal of theses
studies was constrained by limited patient numbers, selection bias and heterogeneity in treatment protocols between the reported series. The sole prospective, RCT comparing open and endovascular treatments found a 53 % mortality among patients treated by either modality. This study was, however, under-powered and contrary to numerous cohort series that show reduced mortality with EVAR. The largest body of evidence was found in a co-operative multi-center cohort study spanning 49 institutions that showed superiority of EVAR over open repair in terms of 30-day mortality. The authors concluded that, within the limitations of the published literature to date, endovascular repair as the primary treatment for rAAA is achievable and appears to be associated with favorable mortality over open repair with appropriate case selection.

On the other hand, other published studies indicated that EVAR is not an established procedure in treating ruptured aneurysms. Vetrhus and associates (2009) noted that repair of AAAs is performed in more than 800 patients annually in Norway. Open repair is an established procedure, but an increasing number of patients have undergone endovascular repair during the last decades. This paper delivered an updated discussion of infra-renal AAA repair. A systematic search was performed in PubMed and literature containing the search terms "abdominal aortic aneurysm" and "mortality" (from 2004 to 2009) was retrieved. The review was based on randomized, multi-center and registry studies examining complications and mortality in endovascular and open repair. Peri-operative mortality is lower in endovascular repair. The initial survival benefit is not sustained over time. The mortality rate is still high in ruptured AAAs, but endovascular repair may improve mortality in selected patients. The authors concluded that even though peri-operative mortality associated with endovascular repair is lower than that of open repair, questions concerning benefit and selection of patients are still left unanswered.

Palombo et al (2009) stated that evidence to support EVAR as first approach for patients with rAAA is drawn from 3 sources:
(i) single-center series, (ii) systematic reviews, and (iii) population-based studies. In order to validate EVAR, this technique was compared to the conventional open repair. These studies were heterogeneous, and often failed to demonstrate any significant difference between EVAR and open repair. More recently, some population-based studies from the United States suggested that there are advantages of EVAR over open repair with regard to 30-day mortality and morbidity. Some bias have influenced the reported results including criteria for choice of EVAR varied across the studies according to the policy of the authors. Therefore, any meta-analysis should be interpreted with caution. Patients' conditions have directed the authors towards a technique instead of the other, namely, pathophysiological factors of the patients, and anatomical conditions of the AAAs. The authors concluded that according to the current literature, the role of EVAR in the management of rAAAs must be further checked; RCTs could provide the evidence to define adequate indication to EVAR.

Karkos et al (2009) documented mortality after endovascular repair of rAAAs. Articles that reported data on mortality after endovascular repair of rAAAs were identified. Only patients with true ruptures were included. Additionally, information on mortality after concurrent open repair was sought. One of the authors reviewed all of the studies and extracted appropriate data. A total of 43 articles were identified, 14 of which were excluded. A total of 29 articles with 897 patients who underwent endovascular repair met the inclusion criteria. Of the patients with available information, 86 % were men; 29 % had been operated on under local anesthesia; 28 % were hemodynamically unstable; 17 % required intra-aortic balloon occlusion; 48 % received bifurcated stent grafts; 6 % had endovascular procedures converted to open repair intra-operatively; and 5.5 % developed abdominal compartment syndrome. In-hospital and/or 30-day mortality ranged between 0 % and 54 % in different series, whereas the pooled mortality after endovascular repair was 24.5 % (95 % CI: 19.8 % to 29.4 %). In 19 studies reporting results of both endovascular and
concurrent open repair from the same unit, the pooled mortality after open repair was 44.4 % (95 % CI: 40.0 % to 48.8 %), and the pooled overall mortality for rAAA undergoing endovascular or open repair was 35 % (95 % CI: 30 % to 41 %). The authors concluded that endovascular repair of rAAAs is associated with acceptable mortality rates. They stated that additional studies are needed to verify these promising results and precisely define the role of endovascular treatment as an additional therapeutic option for rAAAs.

Hinchliffe and colleagues (2009) performed a systematic literature review of EVAR of rAAA from 1994 to 2009. The literature analyzed included systematic reviews and population-based studies of rAAA. A total of 7 systematic reviews were identified, all demonstrating from published data that patients with EVAR of rAAA had significantly reduced mortality compared with controls. Six recently published population-based studies from the United States demonstrated low mortality rates associated with EVAR; however, only a small proportion of rAAAs were treated by EVAR. Systematic reviews and population-based studies both raised concerns about patient selection and publication bias. Two RCTs are in progress, and 1 is due to commence 2009. The authors concluded that the outcome of EVAR in a non-selected patient population remains unknown. One or more definitive RCTs could provide the level I evidence to resolve these issues.

In a systematic review, Chambers et al (2009) examined the clinical effectiveness and cost-effectiveness of EVAR of AAAs in patients at varying levels of risk. The following bibliographic databases were searched (2005 to February 2007): BIOSIS Previews, CINAHL, Cochrane Central Register of Controlled Trials, EMBASE, ISI Proceedings, MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, Science Citation Index and Zetoc Conferences. A systematic review of the clinical effectiveness of EVAR was performed using standard methods. Meta-analysis was employed to estimate a summary measure of treatment effect on relevant outcomes based on intention-to-treat analyses. A second systematic review was undertaken
to identify existing cost-effectiveness analyses of EVAR compared with open surgery and non-surgical interventions. Two new decision models were developed to inform the review.

A total of 6 RCTs were included in the clinical effectiveness review; 34 studies evaluated the role of patients' baseline characteristics in predicting risks of particular outcomes after EVAR. The majority were based on data relating to devices in current use from the EUROSTAR registry. Compared with open repair, EVAR reduces operative mortality (OR 0.35, 95% CI: 0.19 to 0.63) and medium-term aneurysm-related mortality (hazard ratio 0.49, 95% CI: 0.29 to 0.83) but offers no significant difference in all-cause mortality. Endovascular aneurysm repair is associated with increased rates of complications and re-interventions, which are not offset by any increase in health-related quality of life. EVAR Trial 2 comparing EVAR with non-surgical management in patients unfit for open repair found no differences in mortality between groups; however, substantial numbers of patients randomized to non-surgical management crossed-over to receive surgical repair of their aneurysm. The cost-effectiveness systematic review identified 6 published decision models. Both models considered relevant for the decision in the United Kingdom concluded that EVAR was not cost-effective on average compared with open repair at a threshold of 20,000 pounds per quality-adjusted life-year (QALY). Another model concluded that EVAR would be on average more cost-effective than no surgical intervention in unfit patients at this threshold. The Medtronic model concluded that EVAR was more cost-effective than open repair for fit patients at this threshold. The York economic evaluations found that EVAR is not cost-effective compared with open repair on average at a threshold of 30,000 pounds per QALY, with the results very sensitive to model assumptions and the baseline risk of operative mortality. Exploratory analysis to evaluate management options in patients unsuitable for open surgery suggested that the cost-effectiveness of EVAR may be sensitive to aneurysm size and patient's age at operation.

Indicative modelling suggests that EVAR may be cost-effective for small aneurysms in some patient groups. Ongoing RCTs will provide further evidence relating to these patients. The
authors concluded that open repair is more likely to be cost-effective than EVAR on average in patients considered fit for open surgery. Endovascular aneurysm repair is likely to be more cost-effective than open repair for a subgroup of patients at higher risk of operative mortality. These results are based on extrapolation of mid-term results of clinical trials. Evidence does not currently support EVAR for the treatment of ruptured aneurysms.

Jonker et al (2010) stated that thoracic EVAR offers a less invasive approach for the treatment of ruptured descending thoracic aortic aneurysms (rDTAA). Due to the low incidence of this life-threatening condition, little is known about the outcomes of endovascular repair of rDTAA and the factors that affect these outcomes. These investigators retrospectively investigated the outcomes of 87 patients who underwent thoracic EVAR for rDTAA at 7 referral centers between 2002 and 2009. The mean age was 69.8 +/- 12 years and 69.0 % of the patients were men. Hypovolemic shock was present in 21.8 % of patients, and 40.2 % were hemodynamically unstable. The 30-day mortality rate was 18.4 %, and hypovolemic shock (OR 4.75; 95 % CI: 1.37 to 16.5; p = 0.014) and hemothorax at admission (OR 6.65; 95 % CI: 1.64 to 27.1; p = 0.008) were associated with increased 30-day mortality after adjusting for age. Stroke and paraplegia occurred each in 8.0 %, and endoleak was diagnosed in 18.4 % of patients within the first 30 days after thoracic EVAR. Four additional patients died as a result of procedure-related complications during a median follow-up of 13 months; the estimated aneurysm-related mortality at 4 years was 25.4 %. The authors concluded that endovascular repair of rDTAA is associated with encouraging results. The endovascular approach was associated with considerable rates of neurological complications and procedure-related complications such as endoleak. Further improvements of current endovascular devices are needed to reduce the endograft related complications and deaths during follow-up.

In an editorial that accompanied the study by Jonker et al,
Coselli and Gopaldas (2010) stated that "[a]lthough the current use of TEVAR for ruptured thoracic aneurysms remain off label, the success demonstrated by Jonker and colleagues and by several others establishes a strong foundation that would support the use of TEVAR as the primary modality for treating ruptured DTAA in the near future".

A scientific statement on *Surgical management of descending thoracic aortic disease: Open and endovascular approaches* from the American Heart Association (Coady et al, 2010) noted that "[t]reatment 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".

Huddle et al (2009) determined what laboratory values predict the prognosis of patients following EVAR. MEDLINE and Cochrane Library databases were searched. This resulted in 13 relevant articles. Data were pooled, and meta-analyses were performed. A meta-analysis including 5,655 patients showed that pre-operative serum creatinine greater than 1.5 mg/dL was a significant risk indicator for increased 30-day mortality (relative risk 3.0, 95 % CI: 2.3 to 4.1; p < 0.0001). Four other studies showed that other cut-off values of creatinine or glomerular filtration rate (GFR) can predict mortality and complications following EVAR. One study suggested that reduced pre-operative hemoglobin is a risk indicator for reduced long-term survival. Increased serum creatinine, reduced GFR, and reduced hemoglobin are significant and strong predictors of mortality and complications after EVAR.
The authors concluded that current evidence remains limited, and further research is needed to determine conclusively additional laboratory values that may predict the outcome of patients following EVAR.

Linsen et al (2012) performed a systematic review of the current literature to analyze the immediate and follow-up results of fenestrated EVAR (FEVAR) in patients with para-renal AAAs. The Medline, Embase, and Cochrane databases were searched to identify all studies reporting FEVAR of para-renal AAAs published between January 2000 and May 2011. Two independent observers selected studies for inclusion, assessed the quality of the included studies, and performed the data extraction. Studies were selected based on specific pre-defined criteria. Outcomes were technical success (successfully completed procedure with endograft patency, preservation of target vessels, and no evidence of type I or III endoleak at post-procedural imaging), 30-day mortality, all-cause mortality, branch vessel patency, renal impairment, and secondary interventions. Between-study heterogeneity was calculated using I(2) statistics. Pooled estimates were calculated using a fixed-effects (I(2) < 25 %) or a random-effects (I(2) > 25 % to < 50 %) model. A total of 9 studies were included reporting 629 patients who underwent FEVAR for a para-renal AAA, of which 1,622 target vessels were incorporated in an endograft design. Between-study heterogeneity was less than or equal to 41% for all outcomes. The pooled estimate (95 % CI: was 90.4 % (87.7 % to 92.5 %) for technical success, 2.1 % (1.2 % to 3.7 %) for 30-day mortality, and 16 % (12.5 % to 20.4 %) for all-cause mortality. Follow-up was 15 to 25 months. The pooled estimate (95 % CI) during follow-up was 93.2 % (90.4 % to 95.3 %) for branch vessel patency, 22.2 % (16 % to 30.1 %) for renal impairment, and 17.8 % (13.5 % to 22.6 %) for secondary interventions. The authors concluded that promising immediate and mid-term results (up to 2 years) support FEVAR as a feasible, safe, and effective treatment in a relatively high-risk cohort of patients with pararenal AAAs.

Cross et al (2012) stated that FEVAR is a technically challenging
operation. The duration, blood loss, and risk of limb ischemia, contrast-induced nephropathy and re-perfusion injury are likely to be higher than after standard EVAR. Benefits of FEVAR over open repair may be less than those seen with standard infrarenal EVAR. These investigators performed a meta-analysis of observational studies of all published data for FEVAR, with the aim to high-light current issues around the evidence for the potential benefit of FEVAR. A search was performed for studies describing FEVAR for juxta-renal AAAs. Small series of fewer than 10 procedures and studies describing predominantly branched endografts or FEVAR for aortic dissection were excluded. Authors of included papers were contacted to eliminate patient duplication. A total of 11 studies were identified describing a total of 660 procedures. Definitions of aneurysm morphology were variable, and clear inclusion and exclusion criteria were not always documented. Double fenestrations were more common than triple or quadruple fenestrations. Target vessel perfusion rates ranged from 90.5 to 100 %. Eleven deaths occurred within 30 days, giving a 30-day proportional mortality rate of 2.0 %. Morbidity was poorly reported. The authors concluded that FEVAR for repair of supra-renal and juxta-renal aneurysms is a viable alternative to open repair. However, there is no level 1 evidence for FEVAR, and current evidence is weak with many unanswered questions.

In a Cochrane review, Filardo and colleagues (2012) compared long-term survival in patients with AAAs of diameter 4.0 to 5.5 cm who received immediate repair versus routine ultrasound surveillance. For this update the Cochrane Peripheral Vascular Diseases Group searched their Specialised Register (February 2012) and CENTRAL (2012, Issue 1). Reference lists of relevant articles were checked for additional studies and the searches were supplemented by hand-searches of recent conference proceedings and information from experts in the field. Randomized controlled trials in which men and women with asymptomatic AAAs of diameter 4.0 to 5.5 cm were randomly allocated to immediate repair or imaging-based surveillance at least every 6 months. Outcomes had to include
mortality or survival. Two authors abstracted the data, which were cross-checked by the other authors. Due to the small number of trials, formal tests of heterogeneity and sensitivity analyses were not conducted. Four trials with a combined total of 3,314 patients, the UK Small Aneurysm Trial (UKSAT), the Aneurysm Detection and Management (ADAM) trial, the Comparison of Surveillance Versus Aortic Endografting for Small Aneurysm Repair (CAESAR), and the Positive Impact of Endovascular Options for treating Aneurysms Early (PIVOTAL) fulfilled the inclusion criteria. The 4 trials showed an early survival benefit in the surveillance group (due to 30-day operative mortality with surgery) but no significant differences in long-term survival (adjusted hazard ratio (HR) 0.88, 95 % CI: 0.75 to 1.02, mean follow-up 10 years (UKSAT); HR 1.21, 95 % CI: 0.95 to 1.54, mean follow-up 4.9 years (ADAM); HR 0.76, 95 % CI: 0.30 to 1.93, median follow-up 32.4 months (CAESAR); HR 1.01, 95 % CI: 0.49 to 2.07, mean follow-up 20 months (PIVOTAL)). The meta-analyses of mortality at 1 year (CAESAR and PIVOTAL only) and 6 years (UKSAT and ADAM only) revealed a non-significant association (Peto odds ratio at one year 1.15, 95 % CI: 0.59 to 2.25; Peto odds ratio at 6 years 1.11, 95 % CI: 0.91 to 1.34). The authors concluded that these findings from the 4 trials to date demonstrated no advantage to early repair (via open or endovascular surgery) for small AAA (4.0 to 5.5 cm) and suggested that "best care" for these patients favors surveillance. Furthermore, the more recent trials focused on the efficacy of EVAR and still failed to show benefit. Thus, both open and endovascular repair of small AAAs are not supported by currently available evidence.

Brown and associates (2012) evaluated the effectiveness of EVAR against standard alternative management in patients with large AAA. These researchers examined 2 national, multi-center randomized trials -- EVAR trials 1 and 2. Patients were recruited from 38 out of 41 eligible United Kingdom (UK) hospitals. Men and women aged at least 60 years, with an AAA measuring at least 5.5 cm on a CT scan that was regarded as anatomically suitable for EVAR, were assessed for fitness for open repair. Patients considered fit were randomized to EVAR
or open repair in EVAR trial 1 and patients considered unfit were randomized to EVAR or no intervention in EVAR trial 2. The primary outcome was mortality (operative, all-cause and AAA-related). Patients were flagged at the UK Office for National Statistics with centrally coded death certificates assessed by an Endpoints Committee. Power calculations based upon mortality indicated that 900 and 280 patients were required for EVAR trials 1 and 2, respectively. Secondary outcomes were graft related complications and re-interventions, adverse events, renal function, health-related quality of life and costs. Cost-effectiveness analyses were performed for both trials. Recruitment occurred between September 1, 1999 and August 31, 2004, with targets exceeded in both trials: 1,252 randomized into EVAR trial 1 (626 to EVAR) and 404 randomized into EVAR trial 2 (197 to EVAR). Follow-up closed in December 2009 with very little loss to follow-up (1%). In EVAR trial 1, 30-day operative mortalities were 1.8% and 4.3% in the EVAR and open-repair groups, respectively: adjusted odds ratio 0.39 [95% CI: 0.18 to 0.87], p = 0.02. During a total of 6,904 person-years of follow-up, 524 deaths occurred (76 AAA-related). Overall, there was no significant difference between the groups in terms of all-cause mortality: adjusted hazard ratio (HR) 1.03 (95% CI: 0.86 to 1.23), p = 0.72. The EVAR group did demonstrate an early advantage in terms of AAA-related mortality, which was sustained for the first few years, but lost by the end of the study, primarily due to fatal endograft ruptures: adjusted HR 0.92 (95% CI: 0.57 to 1.49), p = 0.73. The EVAR procedure was more expensive than open repair (mean difference of £1,177) and not found to be cost-effective, but the model was sensitive to alternative assumptions. In EVAR trial 2, during a total of 1,413 person-years of follow-up, a total of 305 deaths occurred (78 AAA-related). The 30-day operative mortality was 7.3% in the EVAR group. However, this group later demonstrated a significant advantage in terms of AAA-related mortality, which became apparent only after 4 years: overall adjusted HR 0.53 (95% CI: 0.32 to 0.89), p = 0.02. Sadly, this advantage did not result in any benefit in terms of all-cause mortality: adjusted HR 0.99 (95% CI: 0.78 to 1.27), p = 0.97. Overall, EVAR was more
expensive than no intervention (mean difference of £10,222) and not found to be cost-effective. The authors concluded that EVAR offers a clear operative mortality benefit over open repair in patients fit for both procedures, but this early benefit is not translated into a long-term survival advantage. Among patients unfit for open repair, EVAR is associated with a significant long-term reduction in AAA-related mortality but this does not appear to influence all-cause mortality.

Di and colleagues (2013) noted that the development of endovascular technology has led to the introduction of FEVAR to treat para-renal abdominal aortic aneurysms (PRAAAs) that have been deemed unsuitable for standard endovascular repair. These investigators performed a systematic review and meta-analysis of data from the literature to determine the outcomes of the fenestrated technology. The MEDLINE, EMBASE, and Cochrane databases were searched to identify all studies published in English between January 1996 and May 2011 that reported on FEVAR for PRAAAs. Separate meta-analyses were performed for primary outcomes (i.e., 30-day mortality, technical success rate, primary target vessel patency rate, and 12-month patency rate) and secondary outcomes (i.e., re-intervention rate, target renal artery occlusion rate, and post-operative permanent dialysis rate). Subgroup analyses were performed to determine whether there were differences in outcomes between varying types of studies (prospective or retrospective). Regression analyses were performed to explore associations between outcomes and varying factors (i.e., mid-date of study, study size, and procedure time). A total of 12 studies conducted between 2006 and 2011 and consisting of a total of 776 cases of FEVAR were enrolled. The pooled estimate for 30-day mortality was 2.52 % (95 % CI: 1.55 to 4.08). Technical success was measured to be 92.8 % (95 % CI: 87.5 to 96.0). Primary target vessel patency was 98.3 % (95 % CI: 97.4 to 98.8). Twelve-month target vessel patency was 94.5 % (95 % CI: 92.1 to 96.2). The post-operative re-intervention rate was 17.6 % (95 % CI: 12.0 to 25.1). The target renal artery occlusion rate was 6.1 % (95 % CI: 4.1 to 8.8). The post-operative permanent dialysis rate was 2.6
% (95% CI: 1.5 to 4.4). Subgroup analyses found no significant differences between the major outcomes of the retrospective studies and the prospective studies. Regression analyses suggested that large series had higher 12-month target vessel patency rates than small series. The authors concluded that this study revealed that FEVAR treatment for PRAAAs has acceptable early and mid-term outcomes.

Dijkstra et al (2014) noted that in the past decennium, the management of short-neck infra-renal and juxta-renal aortic aneurysms with FEVAR has been shown to be successful, with good early and mid-term results. Recently, a new fenestrated device, the fenestrated Anaconda (Vascutek, Renfrewshire, Scotland), was introduced. These researchers presented the current Dutch experience with this device. A prospectively held database of patients treated with the fenestrated Anaconda endograft was analyzed. Decision to treat was based on current international guidelines. Indications for FEVAR included an AAA with unsuitable neck anatomy for EVAR. Planning was performed on computed tomography angiography images using a 3-D work-station. Between May 2011 and September 2013, a total of 25 patients were treated in 8 institutions for juxta-renal (n = 23) and short-neck AAA (n = 2). Median AAA size was 61 mm (59 to 68.5 mm). All procedures except 1 were performed with bifurcated devices. A total of 56 fenestrations were incorporated, and 53 (94.6 %) were successfully cannulated and stented. One patient died of bowel ischemia caused by occlusion of the superior mesenteric artery. On completion angiography, 3 type I endoleaks and 7 type II endoleaks were observed. At 1 month of follow-up, all endoleaks had spontaneously resolved. Median follow-up was 11 months (range of 1 to 29 months). There were no aneurysm ruptures or aneurysm-related deaths and no re-interventions to date. Primary patency at 1 month of cannulated and stented target vessels was 96 %. The authors concluded that initial and short-term results of FEVAR using the fenestrated Anaconda endograft are promising, with acceptable technical success and short-term complication rates. Moreover, they stated that growing experience and long-term results are needed to
Raux et al (2014) stated that the benefit of FEVAR compared with open surgical repair (OSR) of complex AAAs (CAAAs) is unknown. These researchers compared 30-day outcomes of these procedures from 2 high-volume centers where FEVAR was undertaken for high-risk patients. Patients undergoing FEVAR with commercially available devices and OSR of CAAAs (total supra-renal/supra-visceral clamp position) were propensity-matched by demographic, clinical, and anatomic criteria to identify similar patient cohorts. Peri-operative outcomes were evaluated using uni-variate and multi-variate methods. From July 2001 to August 2012, a total of 59 FEVAR and 324 OSR patients were identified. After 1:4 propensity matching for age, gender, hypertension, congestive heart failure, coronary disease, chronic obstructive pulmonary disease, stroke, diabetes, pre-operative creatinine, and anticipated/actual aortic clamp site, the study cohort consisted of 42 FEVARs and 147 OSRs. The most frequent FEVAR construct was 2 renal fenestrations, with or without a single mesenteric scallop, in 50% of cases. An average of 2.9 vessels were treated per patient. Uni-variate analysis demonstrated FEVAR had higher rates of 30-day mortality (9.5% versus 2%; p = 0.05), any complication (41% versus 23%; p = 0.01), procedural complications (24% versus 7%; p < 0.01), and graft complications (30% versus 2%; p < 0.01). Multi-variable analysis showed FEVAR was associated with an increased risk of 30-day mortality (OR, 5.1; 95% CI: 1.1 to 24; p = 0.04), any complication (OR, 2.3; 95% CI: 1.1 to 4.9; p =0.01), and graft complications (OR, 24; 95% CI: 4.8 to 66; p < 0.01). The authors concluded that FEVAR, in this 2-center study, was associated with a significantly higher risk of peri-operative mortality and morbidity compared with OSR for management of CAAAs. These data suggested that extension of the paradigm shift comparing EVAR with OSR for routine AAAs to patients with CAAAs is not appropriate. Moreover, they stated that further study to establish proper patient selection for FEVAR instead of OSR is needed before widespread use should be considered.
In a Cochrane review, Jackson et al (2014) compared the clinical outcomes of percutaneous access with standard femoral artery access in elective bifurcated abdominal EVAR. The Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched their Specialised Register (last searched July 2013), CENTRAL (2013, Issue 6) and clinical trials databases. Reference lists of retrieved articles were checked. Only RCTs were considered. The primary intervention was a totally percutaneous endovascular repair. All device types were considered. This was compared against standard femoral artery endovascular repair. Only studies investigating elective repairs were considered. Studies reporting emergency surgery for a rAAA and those reporting aorto-uni-iliac repairs were excluded. All data were collected independently by 2 review authors. Owing to the small number of trials identified, no formal assessment of heterogeneity or sensitivity analysis was conducted. Only 1 trial met the inclusion criteria, involving a total of 30 participants, 15 undergoing the percutaneous technique and 15 treated by the standard femoral cut-down approach. There were no significant differences between the 2 groups at baseline. No mortality or failure of aneurysm exclusion was observed in either group. Three wound infections occurred in the standard femoral cut-down group, whereas none was observed in the percutaneous group. This was not statistically significant. Only 1 major complication was observed in the study, a conversion to the cut-down technique in the percutaneous access group. No long-term outcomes were reported. One episode of a bleeding complication was reported in the percutaneous group. Significant differences were detected in surgery time (percutaneous 86.7 ± 27 minutes versus conventional 107.8 ± 38.5 minutes; p < 0.05). The included study had a small sample size and failed to report adequately the method of randomization, allocation concealment and the pre-selected outcomes. The authors concluded that only 1 small study was identified, which did not provide adequate evidence to determine the safety and effectiveness of the percutaneous approach compared with endovascular aneurysm repairs. This review has identified a clear need for further research into this potentially beneficial
One ongoing study was identified in the search, which may provide an improved evidence base in the future.

Glebova et al (2015) noted that a recent prospective study found that FEVAR was safe and effective in appropriately selected patients at experienced centers. As this new technology is disseminated to the community, it will be important to understand how this technology compares with standard EVAR. These researchers compared the outcomes of FEVAR versus EVAR of AAAs. The American College of Surgeons-National Surgical Quality Improvement Program database from 2005 to 2012 was queried for AAAs (International Classification of Diseases, 9th Revision code 441.4). Patients were stratified according to procedure (FEVAR versus EVAR). A bi-variate analysis was done to assess pre-operative and intra-operative risk factors for post-operative outcomes; 30-day post-operative mortality and complication rates were described for each procedure type. Multi-variable logistic regression was performed to assess the association between the type of procedure and the risk of post-operative complications. A total of 458 patients underwent FEVAR and 19,060 patients underwent EVAR for AAA. Patients undergoing FEVAR were older (p = 0.02) and less likely to have a bleeding disorder (p = 0.046). Otherwise, the incidence of co-morbidities in both groups was similar. Fenestrated EVAR was associated with increased median operative time (156 versus 137 minutes; p < 0.001), and average post-operative length of stay (3.3 versus 2.8 days; p = 0.03). There was a statistically significant increase in overall complications (23.6 % versus 14.3 %; p < 0.001) and post-operative transfusions (15.3 % versus 6.1 %, p < 0.001) and trends toward increased cardiac complications (2.2 % versus 1.3 %; p = 0.09) and the need for dialysis (1.5 % versus 0.8 %; p = 0.08) in the FEVAR group. Mortality (2.4 % versus 1.5 %; p = 0.12) was not statistically different. On multi-variable analysis, FEVAR remained independently associated with the need for post-operative transfusions when operative time was less than 75th percentile (adjusted OR, 1.72; 95 % CI: 1.09 to 2.72; p = 0.02) as well as when operative time was greater than 75th percentile for respective procedures (adjusted OR, 5.33; 95 %
The authors concluded that patients undergoing FEVAR are more likely than patients undergoing EVAR to receive blood transfusions post-operatively and are more likely to sustain post-operative complications. They noted that although mortality was similar, trends toward increased cardiac and renal complications may suggest the need for judicious dissemination of this new technology. They stated that future research with larger number of FEVAR cases are needed to determine if these associations remain.

Capoccia and Riambau (2015) stated that inflammatory AAA (IAAA) is a rare but potentially life-threatening condition that is characterized by marked thickening of the aortic wall, peri-aneurysmal and retro-peritoneal fibrosis, and dense adhesions of adjacent abdominal organs. The pathogenesis of IAAA remains an enigma. The principal objective of invasive or surgical therapy of AAAs is prevention or correction of aortic rupture. Prevention or treatment of AAA rupture by open or endovascular repair is proven by numerous studies published in the literature. However, treatment of IAAA poses a different challenge to surgeons compared with traditional atherosclerotic AAA because of the potential for iatrogenic injury in open repair or, alternatively, potential increased inflammatory response to endoprosthesis implantation. These investigators evaluated the effects of elective endovascular versus open repair for IAAA. The Cochrane Peripheral Vascular Diseases Group Trials Search Coordinator (TSC) searched the Specialised Register (April 2015) and the Cochrane Register of Studies (CRS) (Issue 3, 2015). The TSC searched trial databases for details of ongoing and unpublished studies. The authors sought all published and unpublished RCTs, quasi-RCTs and controlled clinical trials comparing results of elective endovascular or open repair of IAAAs without language restriction. Both review authors independently assessed studies identified for potential inclusion in the review. They planned to conduct data collection and analysis in accordance with the Cochrane Handbook for Systematic Review of Interventions. These researchers identified no studies that met the inclusion criteria. The authors concluded that they found no published RCTs, quasi RCTs or
controlled clinical trials comparing open repair and elective endovascular repair for IAAA, assessing immediate (30-day), intermediate (up to 1-year follow-up) and long-term (more than 1-year follow-up) mortality or complications rates. They stated that high-quality studies evaluating the best treatment for inflammatory abdominal aneurysm repair are needed.

Walker et al (2015) reported their long-term experience with type II endoleaks (T2Ls) management in a large multi-center registry. Between 2000 and 2010, a total of 1,736 patients underwent EVAR, and these investigators recorded the incidence of T2L. Primary outcomes were mortality and aneurysm-related mortality (ARM). Secondary outcomes were change in aneurysm sac size, major adverse events, and re-intervention. During the follow-up (median of 32.2 months; interquartile range [IQR] of 14.2 to 52.8 months), T2L was identified in 474 patients (27.3 %). There were no late AAA ruptures attributable to a T2L. Overall mortality (p = 0.47) and ARM (p = 0.26) did not differ between patients with and without T2L. Sac growth (median of 5 mm; IQR of 2 to 10 mm) was seen in 213 (44.9 %) of the patients with T2L. Of these patients with a T2L and sac growth, 36 (16.9 %) had an additional type of endoleak. Of all patients with T2L, 111 (23.4 %) received re-interventions, including 39 patients who underwent multiple procedures; 74 % of the re-interventions were performed in patients with sac growth. Re-interventions included lumbar embolization in 66 patients (59.5 %), placement of additional stents in 48 (43.2 %), open surgical revision in 14 (12.6 %), and direct sac injection in 22 (19.8 %). The re-intervention was successful in 35 patients (31.5 %). After patients with other types of endoleak were excluded, no difference in overall all-cause mortality (p = 0.57) or ARM (p = 0.09) was observed between patients with T2L-associated sac growth who underwent re-intervention and those in whom T2L was left untreated. The authors concluded that in their multi-center EVAR registry, overall all-cause mortality and ARM were unaffected by the presence of a T2L. Moreover, patients who were simply observed for T2L-associated sac growth had aneurysm-related outcomes similar to those in patients who
underwent re-intervention. They stated that their future work will investigate the most cost-effective ways to select patients for intervention besides sac growth alone.

An UpToDate review on “Endovascular repair of abdominal aortic aneurysm” (Chaer, 2015) states that “Contraindications -- Endovascular repair of AAA is contraindicated in patients who do not meet the anatomic criteria required to place any of the available endografts. Adverse anatomic features include suprarenal or juxtarenal AAA, small caliber vessels, circumferential aortic calcification, and extensive tortuosity. Depending upon the location of the main and accessory renal arteries, endovascular repair may also be contraindicated for the management of AAA associated with horseshoe kidney. A variety of next-generation devices are being developed to treat suprarenal and juxtarenal abdominal aortic aneurysms. A relative contraindication to endovascular aneurysm repair (EVAR) is the inability to comply with the required post-EVAR surveillance. Whether younger patients (less than 60 years of age) who are not at high risk for open surgery should undergo open surgical repair versus EVAR remains controversial. Surveillance over an extended period of time exposes the patient to greater levels of cumulative radiation, and EVAR does not completely eliminate the risk of future aortic rupture. Guidelines from major medical and surgical societies emphasize an individualized approach when choosing endovascular repair, taking into account the patient's age and risk factors for perioperative morbidity and mortality”.

**CT Surveillance after Endovascular (Stent) Aortic Repair:**

MedSolutions guidelines recommend CT surveillance after endovascular (stent) aortic repair at 1 month, 6 months, and 12 months following repair, then every year.

Multi-Branched Stent-Grafts:

Armstrong and associates (2014) stated that patients with large AAAs are usually offered reparative treatment given the high mortality risk. There is uncertainty about how to treat juxta-renal AAAs (JRAAs) or TAAAs. Endovascular repair of an abdominal aortic aneurysm (EVAR) is often seen as safer and easier than OSR. However, endovascular treatment of JRAAs or TAAAs requires specially manufactured stent grafts, with openings to allow blood to reach branches of the aorta. Commissioners are receiving increasing requests for fenestrated EVAR (fEVAR) and branched EVAR (bEVAR), but it is unclear whether or not the extra cost of fEVAR or bEVAR is justified by advantages for patients. In a systematic review and cost-effectiveness analysis, these investigators evaluated the clinical safety, effectiveness, and cost-effectiveness of fEVAR and bEVAR in comparison with conventional treatment (i.e., no surgery) or OSR for 2 populations: (i) JRAAs and (ii) TAAAs. Resources were searched from inception to October 2013, including Medline (OvidSP), Embase (OvidSP) and the Cochrane Central Register of Controlled Trials (Wiley) and, additionally, for cost-effectiveness, NHS Economic Evaluation Database (NHS EED; Wiley) and EconLit (EBSCOhost). Conference abstracts were also searched. Studies were included based on an intervention of either fEVAR or bEVAR and a comparator of either OSR or no surgery. For clinical effectiveness, observational studies were excluded only if they were not comparative, i.e., explicitly selected on the basis of prognosis. For clinical effectiveness, searches retrieved 5,253 records before de-duplication. Owing to overlap between the databases, 1,985 duplicate records were removed. Of the remaining 3,268 records, based on titles and abstracts, 3,244 records were excluded, leaving 24 publications to be ordered. All 24 studies were excluded as none of them satisfied the inclusion criteria -- 16 studies were excluded on study design, 6 on intervention and 2 on comparator; 5 out of 16 studies excluded on study design reported a comparison. However, all
of the studies acknowledged that they had groups that were not comparable at baseline given that they had selectively assigned younger, fitter patients to OSR. Therefore, these studies were considered “non-comparative”. For cost-effectiveness, searches identified 104 references before de-duplication. Owing to overlap between the databases, 34 duplicate records were removed. Of the remaining 70 records, 7 were included for the full assessment based on initial screening. After a full-text review, no studies were included. Because of the lack of clinical effectiveness evidence and difficulty in estimating costs given the rapidly changing and variable technology, a cost-effectiveness analysis (CEA) was not performed. Instead a detailed description of modelling methods was provided. The authors concluded that despite a thorough search, no studies could be found that met the inclusion criteria. All studies that compared either fEVAR or bEVAR with either OSR or no surgery explicitly selected patients based on prognosis, i.e., essentially the populations for each comparator were not the same. The authors recommended that at least 1 clinical trial to provide an unbiased estimate of effect for fEVAR/bEVAR compared with OSR or no surgery. This trial should also collect data for a CEA.

Michel and co-workers (2015) compared 30-day outcomes and costs of fEVAR, bEVAR and OSR for the treatment of complex AAA and TAAA. The multi-center, prospective, registry WINDOW Trial was designed to evaluate fEVAR/bEVAR in high-risk patients with para-renal AA (PRAA)/JRAAA, and infra-diaphragmatic and supra-diaphragmatic TAAA. A control group of patients treated by OSR was extracted from the national hospital discharge database. The primary end-point was 30-day mortality; secondary end-points included severe complications, length of stay, and costs. Mortality was assessed by survival analysis and univariate and multivariate Cox regression analyses using pre- and post-operative characteristics. Bootstrap methods were used to estimate the cost-effectiveness of fEVAR/bEVAR versus OSR. A total of 268 cases and 1,678 controls were included. There was no difference in 30-day mortality (6.7 % versus 5.4 %, p = 0.40), but costs were higher
with fEVAR/bEVAR (€38,212 versus €16,497, p < 0.001). After group stratification, mortality was similar with both treatments for PRAA/JRAAA (4.3 % versus 5.8 %, p = 0.26) and supra-diaphragmatic TAAA (11.9 % versus 19.7 %, p = 0.70), and higher with fEVAR/bEVAR for infra-diaphragmatic TAAA (11.9 % versus 4.0 %, p = 0.010). Costs were higher with fEVAR/bEVAR for PRAA/JRAAA (€34,425 versus €14,907, p < 0.0001) and infra-diaphragmatic TAAA (€37,927 versus €17,530, p < 0.0001), but not different for supra-diaphragmatic TAAA (€54,710 versus €44,163, p = 0.18). The authors concluded that fEVAR/bEVAR did not appear justified for patients with PRAA/JRAAA and infra-diaphragmatic TAAA fit for OSR; but may be an attractive option for patients with PARR/JRAAA not eligible for surgery and patients with supra-diaphragmatic TAAA.

Eagleton and colleagues (2016) evaluated the technical and clinical outcomes of fEVAR/bEVAR for extensive type II and III TAAA. Data from 354 high-risk patients enrolled in a physician-sponsored investigational device exemption (IDE) trial (2004 to 2013) undergoing fEVAR/bEVAR for type II and III TAAA were evaluated. Technical success, peri-operative clinical outcomes, and mid-term outcomes (36 months) for branch patency, re-intervention, aneurysm-related death, and all-cause mortality were analyzed. Data are presented as mean ± standard deviation (S.D.) and were assessed using Kaplan-Meier, univariate, and multivariate analysis; fEVAR/bEVAR incorporating 1,305 fenestration/branches were implanted with 96 % of target vessels successfully stented. Completion aortography showed 2.8 % patients had a type I or III endoleak. Procedure duration (6.0 ± 1.7 versus 5.5 ± 1.6 hours; p < 0.01) and hospital stay (13.1 ± 10.1 versus 10.2 ± 7.4 days; p < 0.01) were longer for type II TAAA. Peri-operative mortality was greater in type II repairs (7.0 % versus 3.5 %; p < 0.001). Permanent spinal cord ischemia (SCI) occurred in 4 % and renal failure requiring hemodialysis occurred in 2.8 % of patients; 27 branches (7.6 %) required re-intervention for stenosis or occlusion; and celiac artery, superior mesenteric artery, and renal artery secondary patency at 36 months was 96 % (95 % CI: 0.93 to 0.99), 98 % (95 % CI: 0.97 to 1.0), and 98 % (95 % CI: 0.97 to 1.0).
A total of 80 endoleak repairs were performed in 67 patients, including 55 branch-related endoleaks, 4 type Ia, 5 type Ib, and 15 type II endoleaks. At 36 months, freedom from aneurysm-related death was 91% (95% CI: 0.88 to 0.95), and freedom from all-cause mortality was 57% (95% CI: 0.50 to 0.63). The treatment of type II TAAA (p < 0.01), age (p < 0.01), and chronic obstructive pulmonary disease (p < 0.05) negatively affected survival. The authors concluded that fEVAR/bEVAR is a robust therapeutic option for patients at increased risk for conventional repair of extensive TAAAs. Technical success and branch patency were excellent, but some patients will require re-intervention for branch-related endoleak. Aneurysm extent portends a higher risk of peri-operative and long-term morbidity and mortality. They stated that additional efforts are needed to improve outcomes and understand the utility of this therapeutic option in the general TAAA population.

In a systematic review and meta-analysis, Hu and colleagues (2016) evaluated the available literature on endovascular repair of TAAA and para-renal aortic aneurysm (PRAA) using multi-branched stent-grafts. Medline, Embase, and Cochrane databases were searched between January 2001 and June 2015 to identify articles related to the use of multi-branched stent-grafts for the treatment of TAAA and PRAA. Articles with less than 4 cases and those on juxta-renal aortic aneurysms were excluded. Meta-analyses were conducted to evaluate 30-day mortality, all-cause mortality, SCI, renal insufficiency, endoleak, target vessel patency, and re-intervention. Of 370 articles screened, only 4 articles encompassing 185 patients (mean age of 71.1 years; 137 men) were aligned with the inclusion criteria. There were 23 PRAAs; the mean aneurysm diameter was 64.5 mm. The Crawford TAAA classification was 10 type I, 47 type II, 37 type III, 58 type IV, and 9 type V; there was 1 Stanford type B dissection in association with a large TAAA. Results of the meta-analyses are reported as proportions and 95% CI. Pooled analysis indicated a technical success rate of 98.9%. As study heterogeneity was significant, random effects models were used for meta-analysis. The rate for 30-day
mortality was 9% (95% CI: 3% to 19%), for all-cause mortality 27% (95% CI: 17% to 38%), endoleaks 10% (95% CI: 1% to 25%), target vessel patency 98% (95% CI: 95% to 99%), SCI 17% (95% CI: 1% to 26%), irreversible SCI 6% (95% CI: 3% to 10%), renal insufficiency 15% (95% CI: 0.8% to 41%), and reinterventions 21% (95% CI: 4% to 47%). The authors concluded that use of multi-branched stent-grafts in the treatment of TAAAs and PRAAs appeared to be feasible and safe based on satisfactory early outcomes in the limited literature available to date. Moreover, they stated that long-term surveillance and further studies are needed to determine the durability of this technique.

Furthermore, an UpToDate review on “Endovascular repair of abdominal aortic aneurysm” (Chaer, 2016) states that “Advanced devices and techniques -- When aneurysmal disease is more extensive, involving the visceral vessels proximally or associated with common or hypogastric artery aneurysms, the complexity of the required endovascular or open repair increases. Fenestrated and branched graft technology is under investigation to manage more challenging anatomy without the need for surgical debranching. The early results using these endografts have been promising, with high rates of successful exclusion of juxta-renal and thoracoabdominal aneurysms, but with an increased risk of visceral artery or stent-branch occlusion”.

<table>
<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
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<tbody>
<tr>
<td>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</td>
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<td>ICD-10 codes will become effective as of October 1, 2015:</td>
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<td>CPT codes covered if selection criteria are met:</td>
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<td>Code</td>
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<td>33880</td>
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**CPT codes not covered for indications listed in the CPB:**

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>+ 34806</td>
<td>Transcatheter placement of wireless physiologic sensor in aneurysmal sac during endovascular repair, including radiological supervision and interpretation, instrument calibration, and collection of pressure data</td>
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<tr>
<td>34839</td>
<td>Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time</td>
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<tr>
<td>CPT Code</td>
<td>Description</td>
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<tr>
<td>34841 - 34844</td>
<td>Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed</td>
</tr>
<tr>
<td>34845 - 34848</td>
<td>Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed</td>
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<tr>
<td>93982</td>
<td>Noninvasive physiologic study of implanted wireless pressure sensor in aneurysmal sac following endovascular repair, complete study including recording, analysis of pressure and waveform tracings, interpretation and report</td>
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**Other CPT codes related to the CPB:**

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<td>33860 - 33877</td>
<td>Thoracic Aortic Aneurysm procedures</td>
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<td>34830 - 34834</td>
<td>Open repair of infrarenal aortic aneurysm or dissection</td>
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**HCPCS codes not covered for indications listed in the CPB:**

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<td>M0301</td>
<td>Fabric wrapping of abdominal aneurysm</td>
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**ICD-10 codes covered if selection criteria are met:**

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<td>A52.01</td>
<td>Syphilitic aneurysm of aorta</td>
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<tr>
<td>I71.01 - I71.6</td>
<td>Aortic aneurysm and dissection</td>
</tr>
<tr>
<td>I72.3</td>
<td>Aneurysm of iliac artery</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


35. F-D-C Reports. TAG thoracic endograft approval makes Gore first to market in U.S. The Gray Sheet. Chevy Chase, MD; F-D-C Reports, Inc.; 2005;31(13).


Greenberg RK, Lytle B. Endovascular repair of


86. Monahan TS, Schneider DB. Fenestrated and branched
stent grafts for repair of complex aortic aneurysms.


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0651
Endovascular Repair of Aortic Aneurysms

There are no amendments for Pennsylvania Medicaid.

www.aetnabetterhealth.com/pennsylvania
Updated 02/2017