Endovascular Grafts for Abdominal Aortic Aneurysms

Policy Number: 7.01.67                     Last Review: 6/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for endovascular grafts for abdominal aortic aneurysms when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
The use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) as a treatment of abdominal aortic aneurysms may be considered medically necessary as a treatment of abdominal aortic aneurysms in any of the following clinical situations:

- an aneurysmal diameter greater than 5.0 cm
- an aneurysmal diameter of 4-5.0 cm that has increased in size by 0.5 cm in the last 6 months
- an aneurysmal diameter that measures twice the size of the normal infrarenal aorta
- a ruptured abdominal aortic aneurysm (See Considerations)

When Policy Topic is not covered
The use of endoprostheses approved by the FDA for all other indications is considered investigational when the above criteria are not met, including but not limited to the following clinical situations:

- Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery
- Treatment of aneurysms that do meet the recommended threshold for surgery in patients who are ineligible for open repair due to physical limitations or other factors

Considerations
For treatment of ruptured abdominal aortic aneurysm with endoprostheses, several factors must be considered including the following:

- The patient must be sufficiently stable to undergo detailed CT examination for anatomic measurements,
- The aneurysm should be anatomically appropriate for endovascular repair, and
- Specialized personnel should be available.

To monitor for leaking of the graft after implantation, patients will typically undergo routine imaging with either computed tomography or ultrasonography every 6 to 12 months, or more frequently if perivascular leaks or aneurysm enlargement is detected.

Coding
The overall procedure essentially involves 4 steps: establishment of vascular access, the introduction of catheters and guidewires into the arterial system, deployment of the endoprosthesis, and radiologic supervision.

1. The following CPT codes describe the establishment of vascular access; either the femoral or iliac arteries are used.
34812: Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision; unilateral
34820: Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision; unilateral

2. Introduction of catheters and guidewires
CPT code 36200 (introduction of catheter, aorta) may be used. Sometimes the renal arteries are catheterized to ensure that the renal arteries are not obstructed by the prosthesis. If this is the case, CPT code 36245 (selective catheter placement, arterial system, each first-order abdominal branch) may be used.

3. The following CPT codes describe the deployment of the prosthesis
34800: Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using aorto-aortic tube prosthesis
34802: ; using modular bifurcated prosthesis (1 docking limb)
34803: ; using modular bifurcated prosthesis (2 docking limbs)
34804: ; using unibody bifurcated prosthesis
34805: ; using aorto-uniliac or aorta-unifemoral prosthesis
34825: Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic aneurysm; initial vessel
34826: ; each additional vessel

4. The following CPT codes describe radiologic supervision
75952: Endovascular repair of infrarenal abdominal aortic aneurysm or dissection, radiological supervision and interpretation
75953: Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic aneurysm, radiological supervision, and interpretation.

It is estimated that less than 5% of patients will be unsuccessfully treated with endovascular techniques to the extent that the patient must undergo urgent or emergent open surgical aneurysm repair. The following CPT codes describe this situation:

34830: Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
34831: ; aorto-bi-iliac prosthesis
34832: ; aorto-bifemoral prosthesis

Effective in 2014, there are category I codes for the use of fenestrated endografts to repair the visceral aorta (34841-34844) and the visceral aorta and infrarenal abdominal aorta (34845-34848). These codes replace the category III codes 0078T-0081T which were deleted.

34841: Endovascular repair of visceral aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34842: including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843: including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844: including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845: Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery) 34846: including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]) 34847: including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]) 34848: including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

Before 2014, there were category III CPT codes that specifically identified the use of fenestrated grafts that allow extensions to be added into the visceral braches of the abdominal aorta. The use of visceral extension prosthesis is reported separately from the use of the fenestrated graft because the number of visceral extensions may vary from 1 to 4, based on the aneurysm anatomy.

0078T: Endovascular repair of abdominal aortic aneurysm, pseudoaneurysm or dissection, abdominal aorta involving visceral vessels.

0079T: Placement of visceral extension prosthesis for endovascular repair of abdominal aortic aneurysm involving visceral vessels, each visceral branch.

Codes 0080T and 0081T describe the radiologic supervision of 0078T and 0079T, respectively.

**Description of Procedure or Service**

Endovascular grafts are minimally invasive alternatives to open surgical repair for treatment of abdominal aortic aneurysms (AAAs). Open surgical repair of AAAs has high morbidity and mortality, and endovascular grafts have the potential to reduce the operative risk associated with AAA repair.

**Background**

The conventional management of a clinically significant abdominal aortic aneurysm consists of surgical excision with placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate of 4%, which may rise to 10% in symptomatic patients. Due to this high mortality rate, endovascular prostheses have been investigated as a minimally invasive, catheter-based alternative to open surgical excision of abdominal aortic aneurysms. These devices are 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 graft currently under investigation—straight grafts, in which both ends are anchored to the infrarenal aorta, and bifurcated grafts, in which the proximal end is anchored to the infrarenal aorta and the distal ends are anchored to the iliac arteries. Recently, fenestrated grafts have also been investigated. These grafts are designed with openings in the wall that can be placed across the renal or celiac arteries while still protecting vessel patency through these critical arteries. In addition, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal.

In 1999, the U.S. Food and Drug Administration (FDA) approved 2 endovascular grafts for use in the abdominal aorta: the EVT Abdominal Aortic Endovascular Grafting System (Guidant Endovascular Technologies) and the AneuRx Prosthesis System (now called AneuRx AAAdvantage Stent Graft - Medtronic Vascular, Inc.). In the Guidant system, the endograft is placed in the aorta and expanded using balloon dilation. The graft is anchored to the vessel wall using sutureless hooks at its superior and inferior ends. The AneuRx system consists of a woven polyester interior surface with a self-expanding nitinol exoskeleton. The radial force of the expanding stent embeds the exoskeleton into the aneurysm wall, and thus constitutes the attachment mechanism. In April 2002, the FDA approved an additional Guidant device, the Ancure Aortoiliac System. The Ancure device consists of a woven polyester graft that is housed within a long flexible delivery tube (catheter) for use in patients whose anatomy is not suited for the use of the single tube or bifurcated endograft device. This version is identical to the earlier Guidant Endovascular Grafting System except that the aortoiliac Ancure grafts
have suture loops on the superior and inferior attachment systems. Several other grafts have been subsequently approved, including the Gore Excluder (2002), the Zenith AAA Endovascular Graft (2003 – now called Zenith Flex AAA Endovascular Graft), the Endologix Powerlink (2004), and the Medtronic Talent Abdominal Stent Graft System (2008).

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. The device is approved for endovascular treatment of aortic or aortoiliac aneurysms which are suitable for endovascular repair with the following:

- Adequate iliac/femoral access compatible with required introduction systems
- Nonaneurysmal infrarenal aortic segment (neck) proximal to the aneurysms with:
  - Length 4 mm and unsuitable for a nonfenestrated graft
  - Diameter <31 mm and 19 mm
  - Angle <45 degrees relative to long axis of aneurysm
  - Angle <45 degrees relative to axis of suprarenal aorta
- Ipsilateral iliac artery fixation site >30 mm in length and between 9 - 21 mm in diameter
- Contralateral iliac artery distal fixation site >30 mm in length and between 7 - 21 mm in diameter.”

Rationale

This policy was created in July 1998 and updated periodically with literature reviews. The most recent literature reviews covers the period through February 26, 2014. This policy is also supported by a 2001 TEC Assessment. (4)

The main potential advantage of endovascular grafts for abdominal aortic aneurysm (AAA) is in offering a less invasive and risky approach to the repair of abdominal aneurysms. This approach has the potential to reduce the relatively high perioperative morbidity and mortality associated with open AAA repair.

Use of endovascular grafts also has potential disadvantages. In particular, there are concerns regarding the durability of the anchoring system, aneurysm expansion, and other late complications related to the prosthetic graft. Aneurysm expansion may result from perivascular leaks, also known as endoleaks, which are a unique complication of endoprostheses. Perivascular leaks may result from an incompetent seal at one of the graft attachment sites, blood flow in aneurysm tributaries (these tributaries are ligated during open surgery), or perforation of graft fabric. (5-8)

Literature Review

EVAR as an alternative to open repair for elective treatment of AAAs

A number of moderate- to large-sized randomized controlled trials (RCTs) have been completed comparing endovascular aneurysm repair (EVAR) with open surgical repair, and these studies comprise the main body of literature on the comparative efficacy of the 2 procedures. (9-11) Early reports of outcomes from these trials demonstrated that the perioperative morbidity and mortality of an endovascular approach were reduced compared with open surgical repair. (12, 13) These results were consistent with prior large observational studies. (14-16) However, the midterm results of these studies suggest that the short-term improvements are not associated with a long-term benefit compared with an open approach. These studies are reviewed next:

Open versus Endovascular Repair (OVER) Trial. (14) Long-term results of the OVER trial were published by Lederle et al in 2012. (17) In this trial, 881 patients with asymptomatic AAAs from multiple Veterans Administration medical centers were randomized to EVAR versus open repair and followed up for a mean of 5.2 years. An early survival advantage was reported for EVAR of up to 3 years, but at final follow-up, mortality was similar between groups (hazard ratio [HR]=0.97, 95% confidence interval [CI], 0.77 to 1.22, p=0.81). On subgroup analysis, differences in mortality were noted according to age.
For patients younger than 70 years, mortality was increased in the EVAR group (HR=1.31, 95% CI, 0.99 to 1.73), while for patients older than 70 years, mortality was reduced in the EVAR group (HR=0.65, 95% CI, 0.43 to 0.98).

**Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial.** (10) This trial enrolled 351 patients who were randomized to either endovascular or open repair. The incidence of aneurysm-related death (ie, within 30 days) was 4.6% in the open repair group and 1.2% in the endovascular repair group. However, after 2 years, the cumulative survival rates were 89.6% for open repair and 89.7% for endovascular repair, due to a higher incidence of late death in the endovascular group. The authors suggest that an open approach may precipitate the mortality of frail patients who were most likely to die in the coming year and that the advantage of an endovascular approach may primarily be to delay death. Alternatively, the late mortality of endovascular repair may relate to its inferior ability to prevent rupture or prevent additional complications, compared with an open approach. If this is true, longer term follow-up is important to determine if the endovascular approach has an inferior outcome over the long term.

Longer term follow-up from this study was reported in 2010. (18) After 6 years of follow-up, the survival rates were similar between the EVAR and open repair groups (68.9% vs 69.9%, respectively; 95% CI, -8.8 to 10.8; p=0.97). Reinterventions were more common in the EVAR group. Freedom from reinterventions was 70.4% for EVAR compared with 81.9% for open repair (95% CI, 2.0 to 21.0; p=0.03).

**Endovascular Aneurysm Repair Versus Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR 1) Trial.** (9) A larger trial, EVAR 1, enrolled 1082 patients 60 years or older with abdominal aneurysms at least 5.5 cm in diameter and randomized them to either elective open or endovascular repair. Similar to the DREAM trial, endovascular repair was associated with an improvement in aneurysm-related survival (4.7% open vs 1.7% at 30 days), but no advantage with respect to all-cause mortality and quality-of-life measures. For example, within 4 years of follow-up, endoscopic repair was associated with a complication rate of 41% compared with only 9% in the surgically treated group. Due to the higher incidence of late complications in those undergoing endovascular repairs, ongoing surveillance is required.

Longer term follow-up from this trial was reported by the EVAR Investigators in 2010. (19) This publication included a total of 1252 patients with aneurysms 5.5 cm or larger randomized to EVAR or open repair. After 8 years of follow-up, there was no difference in survival between the groups (HR=1.03; 95% CI, 0.86 to 1.23). This evidence suggests that the early survival advantage of EVAR is lost over time due to late endograft ruptures, some of which are fatal.

Another follow-up publication from the EVAR-1 trial focused on cardiovascular morbidity and mortality at 5 years post-treatment. (20) The EVAR group had a lower total cardiovascular event rate at all follow-up time points, but the difference over the course of the study did not reach statistical significance (HR=0.83, 95% CI, 0.62 to 1.10). During the period of 6-24 months postsurgery, the EVAR group had a higher rate of cardiovascular events (HR=1.44, 95% CI, 0.79 to 2.62), which attenuated the early benefit of EVAR and led to convergence of events between the 2 procedures. Cardiovascular mortality over the course of the trial was similar between the groups (HR=1.06, 95% CI, 0.83 to 1.36).

**ACE Trial.** This trial (21) compared EVAR with open surgical repair in patients who were low-to-moderate surgical risk. A total of 306 patients were randomized from 25 clinical centers in France. Inclusion criteria included a Society of Vascular Surgery comorbidity score of 0 to 2 and suitable anatomy for EVAR without high-risk features. There were 17 crossovers from open surgery to EVAR (11%) and 4 crossovers from EVAR to open surgery (3%). Median follow-up was 3 years.

Perioperative mortality was 1.3% for the EVAR group and 0.6% for the open surgery group (p=0.12). Survival at 1 year was 95.2% for EVAR and 96.5% for open surgery (p=0.24). At 3 years, survival remained similar at 86.3% for EVAR and 86.7% for open surgery. Major adverse cardiovascular events
were present in 6.7% of EVAR patients compared with 4.0% of open surgery, a difference that was also not significant. Reinterventions were more common in the EVAR group compared with open surgery (16% vs 2.7%, p<0.0001).

Endoleaks were identified on follow-up computed tomography (CT) scanning in 27% of EVAR patients (41/150). There were a total of 10 type I endoleaks; 5 were treated by endoluminal procedures, 2 were treated with open surgery, and 3 were treated by observation. There were a total of 31 type II endoleaks; 8 of these were treated with coil embolization and 23 were left untreated.

Systematic reviews. Agency for Healthcare Research and Quality (AHRQ) published an Evidence-based Practice Center report comparing endovascular and open surgical repair for abdominal aortic aneurysm. (22) Based primarily on the DREAM and EVAR studies discussed here, the report concludes that for aneurysms larger than 5.5 cm, endovascular intervention improves perioperative outcomes compared with open surgical repair, but it has not been shown to improve long-term survival or health status compared with open surgery. The U.K.’s National Institute for Health and Clinical Excellence also updated their guidance following a 2005 systematic review of the safety and efficacy of elective endovascular repair. (23) The guidance states, “Current evidence on the efficacy and short-term safety of stent graft placement in abdominal aortic aneurysm appears adequate to support the use of this procedure.”

A systematic review of RCTs was published in 2012 by Dangas et al (24) This review included 6 trials involving a total of 2899 patients. Combined analysis revealed a lower 30-day mortality rate for the EVAR group (relative risk [RR]=0.35, 95% CI, 0.19 to 0.64). At the longest follow-up, there was not difference in overall mortality (RR=0.99, 95% CI, 0.85 to 1.15), or in AAA-related mortality (RR=1.58, 95% CI, 0.20 to 12.74). There were more reinterventions in the EVAR group at both short-term and long-term follow-up. The relative risk for reinterventions at the longest follow-up was 2.24 (95% CI, 1.58 to 4.08).

A 2014 Cochrane review assessed the evidence on the effectiveness of EVAR compared with open surgery for patients considered fit for surgery.(25) The authors identified 4 trials considered high quality that compared EVAR with open repair (ACE, DREAM, OVER, 1 trials described above; N=2790 patients). In a pooled analysis, short-term mortality (30-day or in-hospital mortality) was significantly lower in patients treated with EVAR (1.4% vs 4.2%, OR=0.33, 95% CI, 0.2 to 0.55, P<0.0001). There were no significant differences in mortality between EVAR and open repair groups at intermediate-term follow-up.

Stather et al conducted a systematic review and meta-analysis of studies of EVAR compared with open surgical repair for AAA with the goal of evaluating longer-term outcomes.(26) The authors included RCTs and validated age-sex matched nonrandomized cohort studies of AAAs that met the following characteristics: compared EVAR with open surgery; contained more than 200 patients for RCTs or more than 2000 patients for cohort studies; and reported on 30-day and longer-term mortality. The final analysis included 11 studies: 9 articles that reported the outcomes from 4 RCTs at different follow-up time points, and 2 nonrandomized studies. The RCTs included 1393 patients who underwent EVAR and 1390 who underwent open surgical repair. The nonrandomized studies included age- and sex-matched cohorts of 23,685 patients who had EVAR and 25,752 who had open repair. Overall, the short-term (30- day or in-hospital) mortality was lower in the EVAR groups (OR=0.36, 95% CI, 0.21 to 0.61). However, at longer term follow up, there were no significant mortality differences between groups (2-year all-cause mortality OR=0.87, 95% CI, 0.72 to 1.06; 4-year or greater all-cause mortality OR=1.11, 95% CI, 0.91 to 1.35). Rates of reintervention were significantly higher in patients treated with EVAR (OR=2.08, 95% CI, 1.27 to 3.39). Similarly, rates of aneurysm rupture were higher in patients treated with EVAR (OR=5.94, 95% CI, 2.33 to 15.14). However, the this result may have been driven by a higher rate of rupture in the EVAR 1 trial than the other RCTs and the nonrandomized trials, which may have reflected surgeon inexperience, along with the fact that the OVER trial used a significant proportion of the Medtronic AneurX devices, which were associated with worsened survival rates.
Quadura et al conducted a systematic review and meta-analysis of RCTs comparing EVAR to open surgery for elective AAA repair for patients who were good surgical candidates. (27) The authors included the DREAM, ACE, EVAR 1, and OVER studies previously discussed. Overall, the 30-day mortality rate was significantly higher in the open repair groups than the EVAR groups (3.2% vs 1.2%; RR=2.81; 95% CI, 1.61 to 4.94). There was no statistically significant difference in long term (at all-cause mortality rates between the open and EVAR repair groups (RR=0.95; 95% CI, 0.84 to 1.10). Reintervention rates were lower in the open repair group than the EVAR group (9.3% vs 18.9%; RR=0.49; 95% CI, 0.40 to 0.60), but there was significant between-study variability (92%), which limits the validity of the pooled relative risk for reintervention rates.

Numerous nonrandomized studies have been performed, including the studies that were originally the basis of FDA approval for endovascular grants. (28, 29) However, these studies add little additional evidence to the RCTs that have been published. A systematic review of nonrandomized studies that compared EVAR versus open surgery in elderly patients, 80 years or older, was published in 2011. (30) This analysis included observational studies of elderly patients who had undergone EVAR and compared results with observational studies of elderly patients undergoing open repair. Pooled analysis revealed that operative mortality was lower in the EVAR group (2.3%) compared with the open surgery group (8.6%) and that EVAR also had lower rates of postoperative cardiac, pulmonary and renal complications. Survival at 3 years was not different between patients undergoing EVAR and open repair (RR=1.10, 95% CI, 0.77 to 1.57).

Section Summary

Evidence from several RCTs supports EVAR as a reasonable alternative to open surgical repair for aneurysms greater than 5.5 cm, or for aneurysms that have high-risk features such as rapid growth. In unselected patients with AAAs appropriate for surgery, EVAR is associated with lower perioperative morbidity and mortality. However, EVAR is associated with a higher rate of longer term complications, including endoleaks and the need for reinterventions. Longer term mortality is similar between EVAR and open surgery at 5 to 8 years of follow-up. For patients who are low risk for open surgery, 1 RCT reports low perioperative morbidity and mortality for both EVAR and open surgery, with no difference between the 2 procedures. Thus, the advantage for EVAR in reduced perioperative morbidity and mortality may not be present for patients who are low risk for surgery.

EVAR as an alternative to open repair for ruptured aneurysms

Emergency EVAR (eEVAR) for ruptured AAAs is being studied as a potential method to decrease the high mortality rate associated with open surgical repair. RCTs are difficult in this area due to the emergent or semiemergent nature of treatment for ruptured aneurysms. As a result, until 2013, the most relevant evidence on this question is from nonrandomized, comparative studies of EVAR versus open surgery. However, there is a high risk for selection bias in uncontrolled studies. Aneurysms that meet the anatomic criteria for EVAR tend to be smaller and less complex than aneurysms that do not meet criteria for EVAR, resulting in the highest risk patients being preferentially treated with open surgery. Some studies have attempted to identify the degree to which selection bias may contribute to apparent favorable outcomes in endovascular EVAR repair by comparing outcomes for patients who underwent open repair in patients who met eligibility for EVAR compared with those who did not. In a study by Krenzien et al, (31) those who were suitable for EVAR had a significantly lower prevalence of in-hospital deaths compared with patients unsuitable for EVAR (25% vs 53%, p=0.02). In contrast, in an observational cohort of 279 patients who underwent open repair of suspected ruptured AAA who were enrolled in parallel to the Amsterdam Acute Aneurysm Trial previously described, 30-day morbidity was not lower among the 71 patients who met criteria for EVAR compared with the 208 patients who did not meet criteria for EVAR (38% vs 30%, p=0.23). (32) Because of the possibility of selection bias, several nonrandomized studies have used patient matching or other methods to reduce selection bias.

Two RCTs were published in 2013 that compare short-term results following endovascular versus open repair for ruptured aneurysms, but longer term follow up is still pending.
RCTs of EVAR compared with open repair for ruptured AAA. In 2013, the IMPROVE investigators reported 30-day follow up results for The Immediate Management of Patients with Rupture: Open Versus Endovascular Repair (IMPROVE) trial. This study randomized 623 patients at 30 centers (29 in the UK, 1 in Canada) with a clinical diagnosis of a ruptured AAA to either an endovascular strategy of immediate CT and eEVAR, with open repair for patients anatomically unsuitable for EVAR (endovascular strategy group), or to the standard treatment of emergency open repair (open repair group). (33) Patients were excluded if they had a previous aneurysm repair, rupture of an isolated internal iliac aneurysm, aorto-caval or aorto-enteric fistulae, recent anatomic assessment of the aorta (for example, awaiting elective EVAR), a diagnosis of connective tissue disorder, or if intervention was considered futile. The study protocol permitted inclusion of hemodynamically unstable patients. Ten patients who were randomized were excluded from data analysis due to breach of inclusion criteria. Three hundred sixteen patients were randomized to EVAR, 275 (87%) of whom had a confirmed diagnosis of ruptured AAA and 174 (64%) were considered anatomically suitable for EVAR. EVAR was attempted in 154 patients, 4 of whom were converted to open repair. Open repair was attempted in 112 other patients (84 anatomically unsuitable for EVAR, 28 crossovers). Sixteen patients died before repair, and 1 patient refused repair and was discharged. Two hundred seventy nine patients were randomized to open repair, 261 (88%) of whom had a confirmed diagnosis of ruptured AAA. Of the open repair randomization group, open repair was attempted in 220 patients (80%), EVAR was attempted in 36 patients (13%), and 19 patients died before repair. For the study's primary outcome, overall 30-day mortality was 35.4% (112/316) in the EVAR group and 37.4% (111/297) in the open repair group (unadjusted odds ratio [OR]=0.92, 95% CI, 0.66 to 1.28; p=0.62). After adjustment for age, sex, and Hardman index, a prognostic score for mortality after ruptured AAA, there were no significant differences on overall 30-day mortality (adjusted OR=0.94, 95% CI, 0.67 to 1.33; p=0.73). Compared with men, women demonstrated a greater benefit from EVAR than men (adjusted OR=0.44 vs 1.18, p value for interaction 0.019). There was a trend for lower mortality in the EVAR group for patients with higher Hardman index and age. Patients in the EVAR group were more likely to be discharged directly to home than those in the open repair group (94% vs 77%; p<0.001).

Also in 2013, Reimerink et al reported results of the Amsterdam Acute Aneurysm trial, a regional multicenter randomized trial to compare EVAR to open repair in the treatment of ruptured AAA. (34) In this trial, patients were recruited from the set of all patients who presented with suspected ruptured AAA at one of 3 trial centers. The other 7 regional hospitals agreed to transfer patients with suspected ruptured AAA to one of the trial centers, if possible. After initial resuscitation, the diagnosis of a ruptured aneurysm was confirmed or rejected based on abdominal ultrasound and/or computed tomographic angiography. Patients who were considered suitable for both EVAR and open repair by the treating vascular surgeon were randomized to either EVAR or open repair. Five hundred twenty patients were diagnosed with ruptured AAA in the trial region; of those, 365 patients were excluded (240 for unfavorable anatomy, 71 with lack of evaluation by computed tomographic angiography, and 54 who were not referred to a trial center). One hundred fifty-five patients were considered to have favorable anatomy; 39 of those were excluded (16 were considered unfit for open repair, 11 for “logistics,” 7 with severe hemodynamic instability after computed tomographic angiography, and 5 who refused surgery). One hundred sixteen patients were randomized, 57 of whom were allocated to the EVAR group and 59 to the open repair group. Ten patients in the EVAR group underwent open repair, and there was 1 perioperative death. In the open repair group, there were 3 diagnoses other than ruptured AAA at surgery and 4 perioperative deaths.

For the study's primary outcome, rates of a composite end point of death and severe complications at 30 days were 42% (24/57) in the EVAR group compared with 47% (28/59) in the open repair group (absolute risk reduction [ARR]=5.4%, 95% CI, -13% to 23%). The 30-day mortality was 21% (12/57) in the EVAR group compared with 25% (15/59) in the open repair group (ARR=4.4%; 95% CI, -11% to 20%). The 2 groups had similar median hospital stay and likelihood of ICU admission. The authors noted that patients in the open repair group had a much lower 30-day mortality rate than was anticipated in the trial's design (25% compared with results from a prior meta-analysis demonstrating a
mortality rate of 48.5% in subjects undergoing open repair of ruptured AAA). As such, the trial may have been underpowered to detect a difference between the groups. In addition, the trial had a high rate of exclusion of patients with ruptured aortic aneurysm, most commonly because of unfavorable infrarenal aortic neck anatomy with absent or very short necks and very wide necks.

Nonrandomized, comparative studies using methods to reduce selection bias. In 2014, Edwards et al published an evaluation of outcomes after EVAR or open repair for ruptured abdominal aortic aneurysms among traditional Medicare beneficiaries discharged from a U.S. hospital from 2001 to 2008. (35) Overall, 10,998 patients underwent ruptured AAA repair, 1126 by EVAR and 9872 by open repair. The population analyzed in this study included 1099 patient pairs who were propensity-score matched based for baseline demographics, comorbid conditions, admission source, and hospital volume of ruptured abdominal aortic aneurysm repair. Short-term mortality was significantly better in the EVAR group (33.8% vs 47.7%, p<0.001). The survival benefit persisted until 4 years before surgery. However, at 36 months before surgery, EVAR patients were more likely to have had AAA-related reinterventions than open repair patients (10.9% vs 1.5%, p<0.001). Strengths of this study include a large sample size, the availability of longer-term follow up data, and the use of propensity-score matching to reduce biased based on observed variables. However, the study is subject to bias if unobserved variables are associated with the decision to perform open repair. In particular, patients with hemodynamic instability may be more likely to undergo open repair, which would bias results in favor of EVAR.

In 2012, Saqib et al published a retrospective comparison of EVAR versus open surgery from a single institution using propensity score matching. (36) Of a sample of 312 patients undergoing repair for a ruptured aneurysm, 37 cases of EVAR were matched with 111 cases of open surgery. Operative mortality rates were numerically lower in the EVAR group but did not reach statistical significance (22% vs 32%, p=0.40). Similarly, complications were somewhat lower in the EVAR group, but the difference was not statistically significant (54% vs 66%, p=0.23). Overall survival at 1 year (50% vs 54%), 2 years (50% vs 52%), and 3 years (42% vs 47%) was similar between the EVAR and open surgery groups (p=0.66 for overall trend).

A different approach to the problem of selection bias was taken by an industry-sponsored study that enrolled 100 consecutive patients across 10 institutions to determine the percentage of patients for whom eEVAR was applicable and to compare mortality and morbidity between the 2 groups. (37) Open surgical repair was performed in 51 patients; in 80% of cases, this was due to a configuration of the neck that was unfavorable for endovascular repair. Patients with severe hemodynamic instability also received open surgical repair. This study found no difference between the 2 groups in either in-hospital (35% to 39%, respectively) or 3-month mortality (40% in the eEVAR group and 42% in the open repair group). Blood loss, time in intensive care, and the duration of mechanical ventilation were lower in patients treated by eEVAR than in those treated by open surgery. Identical mortality rates (53%) were also found in a pilot study with 32 patients randomized to eEVAR or open surgical repair by intention-to-treat analysis. (38)

In addition, endovascular repair requires long-term monitoring and possible reintervention due to endoleaks, graft migration, and aneurysm enlargement. Paraplegia resulting from spinal cord ischemia during eEVAR has also been reported. (39)

One study attempted to address the issue of selection bias by assessing the overall mortality rate in a unit where eEVAR has become the treatment of choice and comparing it with the overall mortality rate of historical controls treated with open surgical repair. (40) For a 2-year period between 2002 and 2004, patients received eEVAR unless they presented with shock or cardiac arrest during transportation to the hospital or if the CT scan indicated an unfavorable anatomic configuration of the aortic neck (short, conical, wide). Fifty-one patients (17 eEVAR and 34 open repair) were treated during the study period; they were compared with a group of 41 patients treated in the previous 2-year period in the same unit and by the same vascular surgeons. The study found a decrease in length of stay in intensive care (5.5 vs 0 days, respectively) and a trend toward a decrease in mortality (59% vs 39%, respectively; p=0.065) with eEVAR. However, the study also found that patients who were considered too unstable
for eEVAR had a 77% mortality rate, while those who were considered unsuitable for eEVAR due to
unsuitable aortic neck anatomy had a 19% mortality rate. These results suggest that the favorable
mortality rates found in uncontrolled eEVAR studies are due to selection bias.

Nonrandomized, comparative studies with unmatched samples. Using a Nationwide Inpatient Sample,
McPhee et al found that rates of endovascular treatment of ruptured AAAs increased from 6% in 2001
to 19% in 2006. (41) They found that eEVAR had a lower overall in-hospital mortality rate than open
repair (32% vs 41%, respectively) and that the effect was amplified when stratified by institutional
volume. (42) Based on analysis of data from Medicare beneficiaries, Egorova et al found that eEVAR
repair of ruptured AAAs had a protective effect (HR=0.86, p=0.006) on long-term survival controlling for
comorbidities, demographics, and volume. Another similar study was an analysis of hospital discharge
databases for California, Florida, New Jersey, and New York. (43) Perioperative mortality rates were
lower for patients treated with eEVAR compared with open surgical repair.

Two nonrandomized, comparative studies using prospectively collected data were reported in 2012.
Mehta et al (44) compared 120 patients who underwent eEVAR with 163 patients who underwent open
surgery. Thirty-day mortality was lower in the eEVAR group (24.2% vs 44.2%, p<.005). The survival
advantage for eEVAR was maintained up to 5 years after treatment. Approximately one fourth of eEVAR
patients required secondary interventions over this time period. In a smaller study, Noorani et al (45)
compared 52 patients receiving eEVAR with 50 patients undergoing open repair from 1 institution. In-
hospital mortality was 12% (6/52) for eEVAR and 32% (16/50) for open surgery. Over a 2-year period of
follow-up, the risk of mortality for the open surgery group was approximately twice that of the eEVAR
group (HR=2.2, 95% CI, 1.1 to 4.6, p=0.01).

A number of publications report on retrospective comparisons of unmatched patients. For example, Ten
Bosch et al (46) performed a retrospective comparison from 1 institution of 25 patients who underwent
eEVAR with 79 patients who underwent open repair. eEVAR was performed if the eEVAR-trained vascular
surgeon was on call and the patient was suitable for eEVAR; otherwise open repair was performed.
Perioperative mortality was 4.0% in the eEVAR group compared with 6.1% in the open repair group
(p>0.99). At 30 days, mortality was lower for the eEVAR group (20.0% vs 45.5%, respectively; p=0.04),
and this survival advantage was maintained at 6 months (28% vs 54.5%, respectively; p=0.04). Median
length of stay was also lower with eEVAR (9.5 days vs 17.0 days, respectively, p=0.03). Another study
that retrospectively compared early postoperative outcomes in patients with ruptured AAAs who
underwent eEVAR or open repair was performed in 1 hospital in the Netherlands. (47) There were a total
of 56 patients treated over a 2-year period, 15 by eEVAR and 41 by open surgery. Thirty-day mortality
was 26% in the eEVAR group compared with 46% in the open surgery group. The overall complication
rate was not different between groups.

Systematic reviews of eEVAR compared with open repair for ruptured AAA.

Qin et al reported results of a systematic review and meta-analysis of emergent eEVAR compared with
open repair for ruptured AAAs that included 2 RCTs, 5 prospective comparative studies, and 11
retrospective comparative studies. (48) The authors included English-language studies that evaluated
outcomes between emergent open and endovascular ruptured AAA repair, with the intervention at the
time of the emergency. In a pooled analysis, for the primary outcome of perioperative mortality, the
patients who underwent eEVAR had significantly lower mortality rates than those who underwent open
repair (pooled OR=0.62, 95% CI, 0.58 to 0.67, p<0.001). There was significant heterogeneity in the
studies.

In another systematic review and meta-analysis of emergent eEVAR compared with open repair for
ruptured AAAs that had less stringent inclusion criteria, Antoniou et al evaluated 41 studies, including
all types of comparative studies (prospective or retrospective observational studies or RCTs). (49) Two
RCTs were included. The meta-analysis included a total of 59,941 patients, 8201 who underwent eEVAR
and 51,740 who underwent open repair. In a pooled analysis, patients who underwent eEVAR had
significantly lower in-hospital mortality than those who underwent open repair (pooled OR=0.56, 95%
CI, 0.50 to 0.64, p<0.01). There was a trend toward shorter length of stay in the EVAR group, but the
difference was not significant.

In a Cochrane Review published before the results of RCTs were available, Dillon et al concluded that
data suggest that endovascular repair is feasible in selected patients with outcomes comparable with
best conventional open surgical repair for ruptured AAAs. (50)

**Section Summary**

For patients with ruptured AAAs to be candidates for endovascular repair, the lesions need to be
suitable for the endovascular devices and patients need to be sufficiently stable to undergo CT
evaluation.

Two RCTs have published short-term outcomes comparing EVAR with open surgery for patients with
ruptured AAA and report that the short-term mortality of EVAR is not significantly different than open
surgery. Longer term outcomes of EVAR compared with open surgery for ruptured aneurysms have not
been reported. Numerous nonrandomized studies and systematic reviews have presented comparative
data on EVAR versus open surgery for the treatment of ruptured AAAs. Most of these publications
report that early mortality is substantially reduced with EVAR compared with open surgery. While some
studies use techniques to reduce the possibility of selection bias, the potential for bias in selecting
patients for EVAR remains.

**EVAR compared with nonsurgical treatment for smaller aneurysms that do not meet current size criteria
for surgery or for patients who are ineligible for open surgery**

There are a limited number of randomized trials that address patients with aneurysms that cannot be
treated by open surgery. This includes patients who have smaller aneurysms that do not meet the size
threshold for open surgery and also patients who cannot undergo open surgery due to prohibitive
operative risk.

**Caesar Trial.** This trial (51) compared the use of EVAR for small AAAs, which did not meet the current
thresholds recommended for intervention, with active surveillance. The study enrolled 360 patients, 50
to 79 years-old, with aneurysms of 4.1 to 5.4 cm. Patients were randomized to early EVAR treatment or
surveillance by ultrasound and/or CT. In the surveillance group, surgery was performed only after the
AAA met current recommendations for intervention (≥5.5 cm, growth 1 cm/year, or symptomatic). If
repair was indicated, EVAR was performed unless the anatomy of the AAA was unsuitable for EVAR, in
which case open repair was performed. Patients were followed for a median of 32.4 months for the
primary outcome of all-cause mortality.

The primary outcome occurred at a lower rate than anticipated, thus limiting the power to detect a
difference. At final follow-up, there was no significant difference in the main end point. Kaplan-Meier
estimates of all-cause mortality were 10.1% for the surveillance group compared with 14.5% for the
EVAR group (HR=0.76; 95% CI, 0.30 to 1.93). Aneurysm-related mortality, aneurysm rupture, and
major morbidity rates were also similar between groups. For patients in the surveillance group, the
Kaplan-Meier estimate of undergoing aneurysm repair was 59.7% at 36 months and 84.5% at 54
months.

A follow-up publication from the Caesar trial reported on quality-of-life (QOL) outcomes. (52) Patients
were assessed with the SF-36 short-form at baseline, 6 months, 12 months, and yearly after that with a
mean follow-up of 31.8 months. Following EVAR, QOL scores in the EVAR arm rose while those in the
observation arm declined. At 6 months’ follow-up, QOL scores in the EVAR group were significantly
higher than in the observation group, with significant differences found for overall score (mean
difference 5.4, p=0.002), physical domain score (mean difference 3.8, p=0.02), and mental domain
score (mean difference 6.0, p=0.001). Over longer periods of time, scores in both the EVAR and
observation group declined, and the differences were not significantly different at time periods of 1 year or longer.

PIVOTAL Trial. (40) The PIVOTAL (Positive Impact of Endovascular Options for Treating Aneurysms Early) trial (53) randomly assigned 728 patients with AAAs of 4 to 5 cm to early EVAR or ultrasound surveillance. Patients were followed for a mean 20 +/- 12 months for the primary outcomes of aneurysm rupture, aneurysm-related death, and overall mortality. At the final follow-up, overall mortality was the same in both groups at a rate of 4.1%. Aneurysm rupture or aneurysm-related death occurred at a low rate and was also the same between groups at a rate of 0.6%. The HR for the primary outcome measures was 0.99 (95% CI, 0.14 to 7.06).

EVAR 2 Trial. (11) The U.K. EVAR Investigators published an RCT of EVAR versus no treatment of AAAs 5.5 cm or larger, but in whom surgery was not an option due to prohibitive surgical risk or patient preference. This trial was the only trial that evaluated patients who were unsuitable for open surgery and compared endovascular repair with no surgical intervention. EVAR 2 randomized 338 patients to either endovascular repair or medical management. Endovascular repair had a considerable 30-day operative mortality and did not improve survival over no intervention. However, the results of this trial are limited, because 20% of patients assigned to medical management underwent elective aneurysm repair in violation of the protocol. In addition, endovascular repair was not performed until a median of 57 days after randomization; during this period, 9 aneurysms ruptured, contributing to the endovascular mortality calculation, biasing results against endovascular repair.

A follow-up publication for this trial reported on longer-term follow-up of 404 patients randomized to EVAR or no treatment. Perioperative mortality in the EVAR group was 7.3%. At the 8-year follow-up point, aneurysm-related mortality was lower in the EVAR group, but overall mortality did not differ (HR=0.99; 95% CI, 0.78 to 1.27). There was a high rate of long-term complications in the EVAR group, with 48% of patients having a graft-related complication, and 27% of patients requiring reintervention for complications.

Accompanying editorials provided the following comments. (54, 55)

- While there has been no difference in overall survival in the EVAR 1 trial, only 24% of patients have reached 4-year follow-up, and further study is required. With an enrolment of 1,082 patients, EVAR 1 is powered to show a difference in overall mortality, while the smaller DREAM trial is not.
- Suitability for endovascular repair depends on anatomic factors. In EVAR 1 only 54% of patients were considered suitable candidates, but this ranged from 6% to 100% across the participating institutions, indicating marked variability in the assessment of anatomic suitability.
- Given that the rate of interventions for endovascular repair increases over time, open repair may be recommended for those with longer life expectancies.
- The numbers of elective aneurysm repairs may grow, considering the recent recommendation of the United States Preventive Services Task Force for screening for abdominal aortic aneurysms in men who have ever smoked. (56)
- It is estimated that approximately 300,000 aneurysms will be identified in this targeted screening population. Many of these aneurysms will measure less than 5.5 cm in diameter and thus will be managed with periodic imaging surveillance, but patients with larger aneurysms will be faced with choosing between open and endovascular repair. The U.S. Agency for Healthcare Research and Quality (AHRQ) has commissioned a technology assessment to compare endovascular and open repair in terms of effectiveness, cost, and quality of life.

Systematic reviews. Based solely on the EVAR 2 trial, the AHRQ report concluded that endovascular repair does not improve survival in patients who are medically unfit for open surgery. (22) As previously discussed, the EVAR 2 trial, and thus the AHRQ assessment, is compromised by the high proportion of patients who crossed over from nonoperative to endovascular repair, and by the number of patients who died in the interval between randomization and treatment with EVAR. Professional guidelines based on both randomized and nonrandomized trials suggest that endovascular repair of infrarenal
aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open operations. (57)

A Cochrane Review summarized the evidence on interventions for small aneurysms, 4.0 to 5.5 cm in size, either by open surgery or EVAR. (58) There were a total of 4 RCTs identified, including the 2 RCTs on EVAR included in this policy review (51, 53) and an additional 2 RCTs on open surgical repair. Combined analysis of the 2 EVAR trials revealed no difference in mortality at 1 year (OR=1.15, 95% CI, 0.59 to 2.25). There was also no survival benefit for the trials of open surgery, nor was there any benefit apparent when all 4 trials were combined.

A subsequent Cochrane Review (previously outlined) compared EVAR with best medical care for patients with AAA who were considered unfit for open repair. (25) Only the EVAR 2 trial met the authors’ inclusion criteria; the authors concluded that “the results of a single trial found no overall short- or long-term benefits of EVAR over no intervention with regard to all-cause mortality.”

Section Summary

The evidence does not indicate that EVAR improves outcomes for patients who are not suitable for open surgery, as judged by aneurysm size and or clinical factors that indicate prohibitive risk for open surgery. For small aneurysms, RCT evidence reports that morbidity and mortality outcomes from surveillance are as good as those from early intervention with EVAR. For patients who are at prohibitive operative risk, 1 RCT reports that EVAR is associated with lower aneurysm mortality but no difference in overall mortality, and that there is a high rate of long-term complications and reinterventions with EVAR. This RCT evidence is limited by a high rate of crossovers, primarily from open surgery to EVAR, which may limit the ability to detect a difference between the 2 treatments.

Ongoing Clinical Trials

A search of the ClinicalTrials.gov website on February 24, 2014, using the keywords “abdominal aortic aneurysm” and “endovascular” identified 30 studies, all of which were nonrandomized studies or completed randomized trials. One larger nonrandomized study addressing the efficacy of EVAR in patients with high surgical risk was identified:

- Endovascular Exclusion of Abdominal Aortic Aneurysms in High Risk Patients (NCT00583414) – This study will assess the efficacy of endovascular stent-graft implantation in subjects with abdominal aortic or iliac aneurysm with high surgical risk (Anticipated mortality greater than 10 percent with conventional surgery). Enrollment is planned for 400 subjects; the planned study completion date is December 2020.

Summary

Evidence from randomized, controlled trials (RCTs) comparing endovascular aneurysm repair (EVAR) with open repair for elective treatment of abdominal aortic aneurysms (AAAs) indicates that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in morbidity and mortality, trials that report outcomes at 5 years or longer show comparable survival for EVAR compared with open repair at these longer time points. Thus, the early advantage of EVAR is balanced out by a higher rate of late complications, leading to comparable long-term outcomes between the 2 procedures. One trial of patients who were of low-to-moderate surgical risk reported that the early benefit of EVAR was not evident in this population, raising the question of whether the early benefits of EVAR extend to patients at lower risk for open surgery. Based on these data, EVAR may be considered medically necessary as an alternative to open surgery in patients who are candidates for both procedures.

For patients with ruptured AAA, evidence from 2 RCTs suggests that short-term mortality from EVAR is comparable with open repair. Further evidence from nonrandomized, matched comparisons report that
EVAR is associated with lower short-term morbidity and mortality. Based on this evidence and recommendations from specialty societies, EVAR may be considered medically necessary for treatment of ruptured aneurysms.

At least 2 RCTs have evaluated EVAR versus no surgical intervention in patients who were not eligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials do not report superior outcomes with EVAR and thus do not support use of EVAR in these patients. As a result, EVAR is considered investigational for patients who are not candidates for open surgery due to aneurysm size or prohibitive surgical risk.

**Practice Guidelines and Position Statements**

Updated guidelines for the management of AAAs were released by the American College of Cardiology and the American Heart Association in 2011 as a focused update to the 2005 guidelines on the management of patients with peripheral artery disease. (59) These guidelines state that:

- Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good surgical candidates (class I recommendation; level of evidence: A).
- Periodic long-term surveillance imaging should be performed to monitor for endoleak, confirm graft position, document shrinkage or stability of the excluded aneurysm sac, and determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms (class I recommendation; level of evidence: A).
- Open aneurysm repair is reasonable to perform in patients who are good surgical candidates but who cannot comply with the periodic long-term surveillance required after endovascular repair. (class IIA recommendation; level of Evidence: C)
- Endovascular repair of infrarenal aortic aneurysms in patients who are at high surgical or anesthetic risk as determined by the presence of coexisting severe cardiac, pulmonary, and/or renal disease is of uncertain effectiveness (class IIb recommendation; level of evidence: B).

Guidelines for the use of EVAR were developed jointly by the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, and the Canadian Interventional Radiology Association. (60) These guidelines state that:

- Indications for EVAR are currently the same as open repair
- Patient preference for EVAR versus open repair should be considered when appropriate
- Endovascular abdominal aortic aneurysm repair should be considered as having an intermediate to high cardiac risk that ranges from 3% to 7%
- There has been increasing use of EVAR for ruptured aneurysms. Achieving optimal EVAR results for ruptured AAA requires establishment of a treatment protocol involving the emergency department, the endovascular team, anesthesiology, and the operating room personnel
- Lifelong imaging surveillance of patients after EVAR is critical for
  - the detection and, if possible, the characterization of endoleaks;
  - evidence of expansion or shrinkage of the residual AAA sac through measurement of aneurysm size, volume calculation, and identification of substantial changes in aneurysm dimensions;
  - detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture; and
  - evaluation of the long-term performance of the endoprosthesis.

The Society for Vascular Surgery (SVS) published guidelines for the treatment of AAAs in 2009. (61) These guidelines indicate that either open surgery or EVAR is an option for patients with aneurysms that meet the current treatment threshold. These guidelines also contained the following statements and recommendations:

- EVAR is progressively replacing open surgery as the treatment of choice, and accounts for more than half of all elective AAA repairs in the U.S.
- Emergent EVAR should be considered for treatment of a ruptured AAA, if anatomically feasible (level of recommendation: strong; quality of evidence: moderate).
- EVAR may be considered for high-risk patients unfit for surgical repair (level of recommendation: weak, quality of evidence: low).

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References**

29. FDA Summary of Safety and Effectiveness. FDA PMA database. Available online at: www.fda.gov/cdrh/pdf/p990020.html
60. Walker TG, Kalva SP, Yeddula K et al. Clinical practice guidelines for endovascular abdominal aortic aneurysm repair: written by the Standards of Practice Committee for the Society of Interventional Radiology and endorsed by the Cardiovascular and Interventional Radiological
### Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>34800</td>
<td>Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using aorto-aortic tube prosthesis</td>
</tr>
<tr>
<td>34802</td>
<td>Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using modular bifurcated prosthesis (one docking limb)</td>
</tr>
<tr>
<td>34803</td>
<td>Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using modular bifurcated prosthesis (two docking limbs)</td>
</tr>
<tr>
<td>34804</td>
<td>Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using unibody bifurcated prosthesis</td>
</tr>
<tr>
<td>34805</td>
<td>Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using aorto-uniliac or aorto-unifemoral prosthesis</td>
</tr>
<tr>
<td>34806</td>
<td>Placement of femoral-femoral prosthetic graft during endovascular aortic aneurysm repair (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>34807</td>
<td>Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral</td>
</tr>
<tr>
<td>34808</td>
<td>Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, or dissection; initial vessel</td>
</tr>
<tr>
<td>34809</td>
<td>Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, or dissection; each additional vessel (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>34810</td>
<td>Endovascular repair of visceral aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)</td>
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<tr>
<td>34811</td>
<td>Endovascular repair of visceral aorta (e.g., 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; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])</td>
</tr>
<tr>
<td>34812</td>
<td>Endovascular repair of visceral aorta (e.g., 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; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])</td>
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<tr>
<td>34813</td>
<td>Endovascular repair of visceral aorta (e.g., 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; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])</td>
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<tr>
<td>34814</td>
<td>Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)</td>
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<tr>
<td>34815</td>
<td>Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)</td>
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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; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

34847  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; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

34848  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; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

75952  Endovascular repair of infrarenal abdominal aortic aneurysm or dissection, radiological supervision and interpretation

75953  Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal aortic or iliac artery aneurysm, pseudoaneurysm, or dissection, radiological supervision and interpretation

34830  Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis

34831  Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bi-iliac prosthesis

34832  Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; aorto-bifemoral prosthesis

The overall procedure essentially involves 4 steps: establishment of vascular access, the introduction of catheters and guidewires into the arterial system, deployment of the endoprosthesis, and radiologic supervision.

1. The following CPT codes describe the establishment of vascular access; either the femoral or iliac arteries are used.
   - 34812: Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision; unilateral
   - 34820: Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision; unilateral

2. Introduction of catheters and guidewires
   - CPT code 36200 (introduction of catheter, aorta) may be used. Sometimes the renal arteries are catheterized to ensure that the renal arteries are not obstructed by the prosthesis. If this is the case, CPT code 36245 (selective catheter placement, arterial system, each first-order abdominal branch) may be used.

3. The following CPT codes described the deployment of the prosthesis
   - 34800: Endovascular repair of infrarenal abdominal aortic aneurysm or dissection; using aorto-aortic tube prosthesis
   - 34802: using modular bifurcated prosthesis (one docking limb)
   - 34803: using modular bifurcated prosthesis (two docking limbs)
   - 34804: using unibody bifurcated prosthesis
   - 34805: using aorto-uniiliac or aorta-unifemoral prosthesis
   - 34825: Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic aneurysm; initial vessel
   - 34826: ; each additional vessel
4. The following CPT code describes radiologic supervision
   - 75952: Endovascular repair of infrarenal abdominal aortic aneurysm or dissection, radiological supervision and interpretation
   - 75953: Placement of proximal or distal extension prosthesis for endovascular repair of infrarenal abdominal aortic aneurysm, radiological supervision, and interpretation.

It is estimated that less than 5% of patients will be unsuccessfully treated with endovascular techniques to the extent that the patient must undergo urgent or emergent open surgical aneurysm repair. The following CPT codes have been introduced to describe this situation:
   - 34830: Open repair of infrarenal aortic aneurysm or dissection, plus repair of associated arterial trauma, following unsuccessful endovascular repair; tube prosthesis
   - 34831: aorto-bi-iliac prosthesis
   - 34832: aorto-bifemoral prosthesis

Effective in 2014, there are category I codes for the use of fenestrated endografts to repair the visceral aorta (34841-34844) and the visceral aorta and infrarenal abdominal aorta (34845-34848). These codes replace the category III codes 0078T-0081T which were deleted.

34841: Endovascular repair of visceral aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34842: including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843: including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844: including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845: Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., 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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34846: including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847: including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848: including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

Before 2014, there were category III CPT codes that specifically identified the use of fenestrated grafts that allow extensions to be added into the visceral branches of the abdominal aorta. The use of visceral extension prosthesis is reported separately from the use of the fenestrated graft because the number of visceral extensions may vary from 1 to 4, based on the aneurysm anatomy.

0078T: Endovascular repair of abdominal aortic aneurysm, pseudoaneurysm or dissection, abdominal aorta involving visceral vessels.

0079T: Placement of visceral extension prosthesis for endovascular repair of abdominal aortic aneurysm involving visceral vessels, each visceral branch.

Codes 0080T and 0081T describe the radiologic supervision of 0078T and 0079T, respectively.

Additional Policy Key Words
N/A
**Policy Implementation/Update Information**

5/1/06  New policy.
5/1/07  No policy statement changes.
6/1/07  Policy statement revised to indicate the use of ruptured abdominal aortic aneurysms is investigational.
5/1/08  No policy statement changes.
5/1/09  No policy statement changes.
5/1/10  Policy statement revised; may be considered medically necessary for ruptured abdominal aortic aneurysms.
5/1/11  No policy statement changes.
5/1/12  No policy statement changes.
5/1/13  No policy statement changes.
6/1/13  No policy statement changes.
4/1/14  Removed deleted codes 0078T, 0079T, 0080T, 0081T.
6/1/14  Added code 34805, updated coding information regarding endograft repair and deletion of category III codes 0078T-0081T. The second policy statement was editorially revised to clarify that situations that do not meet the criteria in the first policy statement would be considered investigational. No change to the intent of the policy.

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