Endovascular Stent Grafts for Abdominal Aortic Aneurysms

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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 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])

Effective in 2015, a code was created for the extra physician work involved in planning a patient-specific fenestrated visceral aortic endograft:

34839: Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time.

Code 34839 cannot be reported on the day before or the day of the endovascular repair procedure.

### Description of Procedure or Service

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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.

In individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. Evidence from RCTs comparing endovascular aneurysm repair (EVAR) with open repair for elective treatment of AAAs indicates that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in morbidity and mortality, trials reporting outcomes at 5 years or longer have shown comparable survival rates for EVAR and open repair. Thus, the early advantage of EVAR is balanced out by a higher rate of late complications over the long term. In addition, 1 trial of patients at 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 as an alternative to open surgery in patients who are candidates for both procedures. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

In individuals who have ruptured AAAs who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. For patients with ruptured AAAs, evidence from 4 RCTs and a patient-level meta-analysis indicates that short- and intermediate-term survival following EVAR is comparable with open repair. Evidence from RCTs and nonrandomized matched comparisons has shown that EVAR is associated with lower perioperative morbidity. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

In individuals who have AAAs not eligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. At least 2 RCTs have compared EVAR to no surgical intervention in patients ineligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials did not report superior outcomes with EVAR and thus do not support use of EVAR in
this population. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

**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.

**Regulatory Status**
A large number of endovascular grafts have been approved for use for treatment of AAAs by the U.S. Food and Drug Administration (FDA).

- The EVT Abdominal Aortic Endovascular Grafting System (1999, Guidant Endovascular Technologies) 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® Prosthesis System (1999, now called AneuRx AAAdvantage Stent Graft; Medtronic Vascular). 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, an additional Guidant device, the Ancure® Aortoiliac System, was approved by FDA. 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.
- The Gore® Excluder® (2002)
- The Zenith® AAA Endovascular Graft (2003; now called Zenith Flex AAA Endovascular Graft),
- The Endologix PowerLink® (2004),
The Endologix AFX® endovascular system (2011)

The Ovation™ Abdominal Stent Graft System (2012, TriVascular Inc.), a lower-profile stent graft that uses a postimplantation polymer deployment system to seal the device to the aorta, was approved by FDA for endovascular repair of AAAs with suitable anatomy(2)

The Zenith® Fenestrated AAA Endovascular Graft (2012, Cook Medical), a graft that extends across the visceral arteries, was approved by FDA with the adjunctive Zenith Alignment Stent. The graft is approved for endovascular treatment of aortic or aortoiliac aneurysms that 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
    - < 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."

The Aorfix™ AAA Flexible Stent Graft System (2013, Lombard Medical).(3)

Rationale
This evidence review was created in July 1998, updated with a TEC Assessment in 2001,(4) and has since been updated periodically with literature reviews of the MEDLINE database. The most recent literature update covers the period through March 25, 2016.

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)
Endovascular Aneurysm Repair 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. 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. These results were consistent with prior large observational studies. 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:

Randomized Controlled Trials

Open Versus Endovascular Repair Trial

Long-term results of the Open Versus Endovascular Repair (OVER) trial were published by Lederle et al in 2012. 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 higher in the EVAR group (HR=1.31; 95% CI, 0.99 to 1.73), while for patients older than 70 years, mortality was lower in the EVAR group (HR=0.65; 95% CI, 0.43 to 0.98).

Dutch Randomized Endovascular Aneurysm Management Trial

The Dutch Randomized Endovascular Aneurysm Management (DREAM) trial enrolled 351 patients who were randomized to either endovascular or open repair. The incidence of aneurysm-related death (i.e., 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. After 6 years of follow-up, the survival rates were similar between the EVAR (68.9%) and open repair groups (69.9%; difference 1 percentage point, 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 (difference 11.5 percentage points, 95% CI, 2.0 to 21.0; p=0.03).

**Endovascular Aneurysm Repair Versus Open Repair in Patients With Abdominal Aortic Aneurysm Trial**

*Endovascular Aneurysm Repair Versus Open Repair in Patients With Abdominal Aortic Aneurysm (EVAR 1) trial, 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.*(9) 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 (QOL) 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 follow-up included 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 posttreatment.(20) The EVAR group had a lower total cardiovascular event rate at all follow-up time points, but the difference during the study was not statistically significant (HR=0.83; 95% CI, 0.62 to 1.10). During the period of 6 to 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).

**Anevrysme de l’aorte abdominale: Chirurgie versus Endoprothese Trial**

*The Anevrysme de l’aorte abdominale: Chirurgie versus Endoprothese (ACE) trial compared EVAR with open surgical repair in patients who were low-to-moderate surgical risk.*(21) 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 (16%) compared with open surgery (2.7%; p<0.001).

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.

Nonrandomized Comparative Studies
In 2015, Schermerhorn et al published a propensity-matched study of EVAR versus open repair in 79,932 Medicare patients.(22) Matching was based on demographic and clinical variables available for 2 years prior to the index procedure. Analysis of Medicare data showed that patients treated with EVAR had lower perioperative mortality (1.6% vs 5.2% p<0.001) and improved survival through the first 3 years of follow-up compared to patients treated with open repair. Survival rates between 3 and 8 years of follow-up did not differ between groups. Reasons for interventions through 8 years of follow-up differed, and were related to the management of the aneurysm after EVAR versus laparotomy after open repair. Aneurysm rupture occurred in a significantly greater proportion of patients after endovascular repair (5.4%) than in patients who had open repair (1.4%) through 8-year follow-up (p<0.001). Interpretation of these data is limited by the potential for selection bias. While this study used propensity matching to reduce selection bias, the potential for bias in selecting patients for EVAR remains.

Systematic Reviews
A 2014 Cochrane review assessed the evidence on the effectiveness of EVAR compared with open surgery for patients considered fit for surgery.(23) The authors identified 4 trials considered high quality that compared EVAR with open repair (ACE, DREAM, OVER, EVAR 1 trials previously described; total 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%; odds ratio [OR], 0.33; 95% CI, 0.2 to 0.55; p<0.001). 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.(24) 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 patients 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 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, 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.

Qadura et al conducted a systematic review and meta-analysis of RCTs comparing EVAR with open surgery for elective AAA repair for patients who were good surgical candidates. The authors included the DREAM, ACE, EVAR 1, and OVER trials. Overall, the 30-day mortality rate was significantly higher in the open repair groups (3.2%) than the EVAR groups (1.2%; relative risk [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 (9.3%) than in the EVAR group (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.

Similarly, several earlier systematic reviews and meta-analyses of RCTs comparing EVAR and open surgery reported reduced short-term mortality with EVAR, but no evidence of long-term benefits.

Numerous nonrandomized studies have been performed, including the studies that were originally the basis of U.S. Food and Drug Administration (FDA) approval for endovascular grants. However, these studies add little additional evidence to the RCTs published on the comparative effectiveness of EVAR versus open repair. A systematic review of nonrandomized studies that compared EVAR versus open surgery in elderly patients, 80 years or older, was published in 2011. 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 did not differ between patients undergoing EVAR and open repair (RR=1.10; 95% CI, 0.77 to 1.57).

Section Summary: Endovascular Aneurysm Repair as an Alternative to Open Repair for Elective Treatment of AAAs
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 AAAs**

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 semi-emergent 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, 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).(32) 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 (described below), 30-day morbidity was not lower among the 71 patients who met criteria for EVAR (38%) compared with the 208 patients who did not meet criteria for EVAR (30%; p=0.23).(33) 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 and 2014 that compare short-term results following endovascular versus open repair for ruptured aneurysms. One-year follow-up from 1 of the trials (IMPROVE, described next) was published in 2015. Thirty-day and 1-year follow-up for a pseudo-randomized trial that compared EVAR with open surgical repair in patients who qualified for EVAR was published in 2015.

**RCTs of EVAR Compared With Open Repair for Ruptured AAAs**

**Immediate Management of Patients With Rupture: Open Versus Endovascular Repair Trial**

Thirty-day follow up results for the Immediate Management of Patients with Rupture: Open Versus Endovascular Repair (IMPROVE) trial. One-year outcomes were reported in 2015.(34) This study randomized 623 patients at 30 centers (29 in the U.K., 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). (35) 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 (13%) patients, 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 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 (adjusted OR=0.44), women demonstrated a greater benefit from EVAR (adjusted OR=1.18; p=0.019 for interaction). There was a trend for lower mortality in the EVAR group for patients with higher Hardman index and age. Patients in the EVAR group (94%) were more likely to be discharged directly to home than those in the open repair group (77%; p<0.001).

For the study’s primary 1-year outcome, survival data were available for 611 of 613 patients randomized. All-cause mortality did not differ significantly for the EVAR (41.1%) and the open repair groups (45.1%; OR=0.85; 95% CI, 0.62, 1.17; p=0.325), with similar reintervention rates in each group. (34) The EVAR group (17 days) had shorter hospital stays than the open repair group (26 days; p<0.001). QOL, measured with the EuroQoL questionnaire, was higher in the EVAR group than in the open group, with a mean difference of 0.087 (95% CI, 0.017 to 0.158) at 3 months and 0.068 (95% CI, -0.004 to 0.140) at 12 months. This exceeded the minimally clinically important difference of 0.03.

**Amsterdam Acute Aneurysm Trial**

Also in 2013, Reimerink et al reported results of the Amsterdam Acute Aneurysm (AAA) trial, a regional multicenter randomized trial to compare EVAR with open repair in the treatment of ruptured AAA. (36) In this trial, patients were recruited from the set of all patients who presented with suspected ruptured AAA at 1 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 tomography angiography (CTA). 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 CTA, 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 CTA, 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% vs 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.

Endovasculaire ou Chirurgie dan les Aneuvysmes aorto-iliaques Rompus
In 2015, Desgranges et al reported the 30-day and 1-year results of the multicenter Endovasculaire ou Chirurgie dan les Aneuvysmes aorto-iliaques Rompus (ECAR) pseudo-randomized trial.(37) A total of 107 patients were assigned by alternating weeks to EVAR (n=56) or open repair (n=51). Power analysis indicated that 80 patients per group would be required to detect a 20% reduction in mortality, however, enrollment for the trial was terminated after 5 years. Patients were included if they had a ruptured aortic, aorto-iliac, or iliac aneurysm, met clinical and anatomic criteria for both EVAR and open repair, and were hemodynamically stable. Assignment also included the availability of a qualified surgeon (≥15 EVAR procedures) and facilities. During the study period 417 patients were treated for ruptured aorto-iliac aneurysms, of which 32% qualified for EVAR (56 included, 116 not included). Baseline characteristic were similar between the EVAR and open repair study groups. There was no significant difference between EVAR and open repair group for the primary outcome of mortality at 30 days (18% vs 24%, p=0.239) or at 1 year (30% vs 35%,
respectively, 0.296), although the study was underpowered to detect a difference of this magnitude. The lower than expected mortality in the open repair group may have been due to the exclusion of patients with hemodynamic instability or unfavorable anatomic criteria. In spite of a longer delay to repair with EVAR compared to open surgery (2.9 hours vs 1.3 hours, p<0.005), EVAR resulted in a reduction in respiratory support time (59.3 hours vs 180.3 hours, p=0.007), pulmonary complications (15.4% vs 41.5%, p=0.05), total blood transfusion (6.8 units vs 10.9 units, p=0.020), and duration of intensive care unit stay (7 days vs 11.9 days, p=0.010).

Nonrandomized Comparative Studies
A number of nonrandomized comparative studies, published before and since the results of the RCTs previously describe, have attempted to evaluate outcomes after emergent EVAR. These studies are all subject to the risk of selection bias, as described previously. The strongest study designs use methods to reduce or account for selection bias.

In 2014, Edwards et al published an evaluation of outcomes after EVAR or open repair for ruptured AAAs among traditional Medicare beneficiaries discharged from a U.S. hospital from 2001 to 2008. 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 (10.9%) were more likely to have had AAA-related reinterventions than open repair patients (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 bias 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. 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 were not statistically different (22% vs 32%, p=0.40). Similarly, complications were somewhat lower in the EVAR group, though the difference was not statistically significant (54% vs 66%, p=0.23). Overall survival rates at 1 year (50% vs 54%), 2 years (50% vs 52%), and 3 years (42% vs 47%) were similar between 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. 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% in the eEVAR group vs 39% in the open repair group) or 3-month mortality (40% in the eEVAR group vs 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.

One study attempted to address selection bias by assessing the overall mortality rate in a unit where eEVAR had become the treatment of choice and comparing it to the overall mortality rate of historical controls treated with open surgical repair. 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, 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 days 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.

A large number of other studies have used data from prospective and retrospective observational studies or administrative registries to compare outcomes after eEVAR with open repair for ruptured AAAs. These studies have generally reported lower rates of short-term mortality with EVAR compared with open repair, but are subject to bias in the selection of patients for EVAR.

**Systematic Reviews of EVAR Compared With Open Repair for Ruptured AAAs**

In 2015, Sweeting et al published a patient-level meta-analysis of 3 RCTs (total N=836 patients) that compared EVAR with open repair for ruptured AAAs. To have a more uniform comparison, 90-day data from only the patients who were anatomically suitable for EVAR from the IMPROVE trial were analyzed along with patient-level data from the AAA and ECAR trials (described above). There was no survival benefit from EVAR in pooled analysis at 90 days (OR=0.85; 95% CI, 0.64 to 1.13). However, pooled analysis confirmed the finding from IMPROVE that women benefited more than men from an endovascular strategy (ratio of OR=0.49; 95% CI, 0.24 to 0.99). Pooled analysis also confirmed the individual
findings of the 3 trials that hospital length of stay was shorter after EVAR than after open repair (HR=1.24; 95% CI, 1.04 to 1.47).

In a 2014 Cochrane review, which was an update of a 2007 Cochrane review, Badger et al reviewed RCTs comparing eEVAR with surgical repair for clinically or radiologically diagnosed ruptured AAAs.(51) The authors included 3 RCTs with a total of 761 patients, which consisted of the IMPROVE and AAA trials, along with a small 2006 pilot RCT (N=32 patients). The overall risk of bias was low, but 1 study did not adequately report random sequence generation, putting it at risk of selection bias, 2 studies did not report on outcomes identified in their protocol, indicating reporting bias, and 1 study was underpowered.

For the primary outcome of short-term (30-day or in-hospital mortality), There was no significant difference between open repair and EVAR (OR=0.91; 95% CI, 0.67 to 1.22; p=0.52).

Van Beek et al conducted a systematic review and meta-analysis of RCTs, observational studies, and administrative registries to compare emergent EVAR with open repair for ruptured AAAs.(52) The study included 3 RCTs, 21 observational studies, and 8 administrative registries. In pooled analysis of the RCTs, rates of death in the short term (30-day or in-hospital) after EVAR did not differ significantly from those after open repair (OR=0.90; 95% CI, 0.65 to 1.24). Observational studies and administrative registries were considered to be at high risk of bias. In pooled analysis of the observational studies, the OR for death after EVAR compared with open repair was 0.44 (95% CI, 0.37 to 0.53); for administrative registries, the pooled OR for death after EVAR compared with open repair was 0.54 (95% CI, 0.47 to 0.62).

Earlier systematic reviews and meta-analyses with less-stringent inclusion criteria that included RCTs and prospective and retrospective observational studies reported lower short-term mortality with EVAR than with open repair.(53,54)

**Section Summary: EVAR as an Alternative to Open Repair for Ruptured AAAs**

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. Three RCTs have published outcomes comparing EVAR with open surgery for patients with ruptured AAA and reported that the 30-day and 1-year mortality for EVAR did not differ significantly from 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 reported that early mortality is substantially reduced with EVAR compared with open surgery. While some studies used techniques to reduce the possibility of selection bias, the potential for bias toward EVAR remains.
EVAR Compared With Nonsurgical Treatment for Smaller Aneurysms Not Meeting Current Size Criteria for Surgery or for Patients Ineligible for Open Surgery
Few randomized trials 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.

EVAR for Smaller Aneurysms

Randomized Controlled Trials
The CAESAR trial compared the use of EVAR for small AAAs, which did not meet the current thresholds recommended for intervention, with active surveillance.(55) 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 QOL outcomes.(56) Patients were assessed with the 36-Item Short-Form Health Survey 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-month 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 [MD], 5.4, p=0.002), physical domain score (MD=3.8; p=0.02), and mental domain score (MD=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.

The PIVOTAL (Positive Impact of Endovascular Options for Treating Aneurysms Early) trial randomly assigned 728 patients with AAAs of 4 to 5 cm to early EVAR or ultrasound surveillance.(57) Patients were followed for a mean 20 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).

**Systematic Reviews**
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) Four RCTs were identified, including 2 RCTs on EVAR (previously discussed)(55,57) and 2 others 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 four trials were combined.

**EVAR for Patients at Prohibitive Surgical Risk**
A single RCT has compared endovascular repair for AAAs with no surgical intervention in patients who are unsuitable for open surgery. 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.(11) 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 longer term follow-up publication for this trial reported on 404 patients randomized to EVAR or no treatment. Perioperative mortality in the EVAR group was 7.3%. At the 8-year follow-up, 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.

Based solely on the EVAR 2 trial, a 2005 Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center report comparing endovascular and open surgical repair for abdominal aortic aneurysm concluded that endovascular repair does not improve survival in patients who are medically unfit for open surgery.(26) 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.(59)
A subsequent Cochrane Review (previously discussed) compared EVAR to best medical care for patients with AAA who were considered unfit for open repair. Only the EVAR 2 trial met authors’ inclusion criteria; they 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.”

Lim et al retrospectively compared outcomes after EVAR for 75 patients considered high risk by the criteria used in the EVAR 2 trial with 75 considered normal risk. While high-risk patients had larger aneurysms on average and a higher prevalence of comorbid diseases, perioperative mortality (0% for high risk vs 1.2% for normal risk; p=1.0) and early complication rates (4% for high risk vs 6% for normal risk; p=0.08) were similar between groups. These findings suggest that EVAR may be feasible with reasonable outcomes in patients at high medical risk, but conclusions that may be drawn from this study are limited by its retrospective nature.

**Section Summary: EVAR Compared With Nonsurgical Treatment for Smaller Aneurysms Not Meeting Current Size Criteria for Surgery or for Patients Ineligible for Open Surgery**

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 has reported 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 and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<td>Endovascular Exclusion of Abdominal Aortic Aneurysms in High Risk Patients</td>
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</table>

NCT: national clinical trial.

**Summary of Evidence**

In individuals who have abdominal aortic aneurysms (AAAs) eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. Evidence from RCTs comparing endovascular aneurysm repair (EVAR) with open repair for elective treatment of
AAAs indicates that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in morbidity and mortality, trials reporting outcomes at 5 years or longer have shown comparable survival rates for EVAR and open repair. Thus, the early advantage of EVAR is balanced out by a higher rate of late complications over the long term. In addition, 1 trial of patients at 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 as an alternative to open surgery in patients who are candidates for both procedures. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

In individuals who have ruptured AAAs who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. For patients with ruptured AAAs, evidence from 4 RCTs and a patient-level meta-analysis indicates that short- and intermediate-term survival following EVAR is comparable with open repair. Evidence from RCTs and nonrandomized matched comparisons has shown that EVAR is associated with lower perioperative morbidity. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

In individuals who have AAAs not eligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related morbidity and mortality. At least 2 RCTs have compared EVAR to no surgical intervention in patients ineligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials did not report superior outcomes with EVAR and thus do not support use of EVAR in this population. The evidence is sufficient to determine qualitatively that the technology is unlikely to improve the net health outcome.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**European Society of Cardiology**
In 2014, the European Society of Cardiology issued guidelines on the diagnosis and treatment of aortic diseases, including AAAs. These guidelines state: “In patients with suitable anatomy, EVAR is associated with a 66% reduction in operative mortality, a benefit that is lost during follow-up, and which comes at the cost of an increased reintervention rate. For all other AAA aneurysms that are not suitable for EVAR, open repair remains the reference standard.”

**American College of Cardiology Foundation and American Heart Association**
Updated guidelines for the management of AAAs were released by the American College of Cardiology Foundation and the American Heart Association in 2011 as a
focused update to the 2005 guidelines on the management of patients with peripheral artery disease.\(^{(62)}\) 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).

**Society of Interventional Radiology et al**

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.\(^{(63)}\) 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.

**Society for Vascular Surgery**

The Society for Vascular Surgery published guidelines for the treatment of AAAs in 2009.\(^{(64)}\) 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 United States.
- 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).

U.S. Preventive Services Task Force Recommendations
Not applicable.

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:

**Billing Coding/Physician Documentation Information**

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<td>34701</td>
<td>Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)</td>
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selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (eg, for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting, when performed, unilateral; for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation)

34708 Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting, when performed, unilateral; for other than rupture including temporary aortic and/or iliac balloon occlusion, when performed (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, traumatic disruption)

34709 Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed, per vessel treated (List separately in addition to code for primary procedure)

34710 Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed; initial vessel treated

34711 Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed; each additional vessel treated (List separately in addition to code for primary procedure)

34712 Transcatheter delivery of enhanced fixation device(s) to the endograft (eg, anchor, screw, tack) and all associated radiological supervision and interpretation

34713 Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral (List separately in addition to code for primary procedure)

34714 Open femoral artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral (List separately in addition to code for primary procedure)
Open axillary/subclavian artery exposure for delivery of endovascular prosthesis by infraclavicular or supraclavicular incision, unilateral (List separately in addition to code for primary procedure)

Open axillary/subclavian artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by infraclavicular or supraclavicular incision, unilateral (List separately in addition to code for primary procedure)

Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral

Placement of femoral-femoral prosthetic graft during endovascular aortic aneurysm repair (List separately in addition to code for primary procedure)

Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral

Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time

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; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)

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

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

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

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 one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)

34846 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 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

36200 Introduction of catheter, aorta

36245 Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family

ICD-10 Codes

I71.3 Abdominal aortic aneurysm, ruptured
171.4 Abdominal aortic aneurysm, without rupture
172.3 Aneurysm of iliac artery

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 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])

Effective in 2015, a code was created for the extra physician work involved in planning a patient-specific fenestrated visceral aortic endograft:

34839: Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time.

Code 34839 cannot be reported on the day before or the day of the endovascular repair procedure.

Codes 34800, 34802, 34803, 34804, 34805, 34825, 34826 were deleted as of 1/1/2018.

**Additional Policy Key Words**
N/A

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>5/1/06</td>
<td>New policy.</td>
</tr>
<tr>
<td>5/1/07</td>
<td>No policy statement changes.</td>
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<tr>
<td>6/1/07</td>
<td>Policy statement revised to indicate the use of ruptured abdominal aortic aneurysms is investigational.</td>
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<tr>
<td>5/1/08</td>
<td>No policy statement changes.</td>
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<tr>
<td>5/1/09</td>
<td>No policy statement changes.</td>
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<tr>
<td>5/1/10</td>
<td>Policy statement revised; may be considered medically necessary for ruptured abdominal aortic aneurysms.</td>
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<tr>
<td>5/1/11</td>
<td>No policy statement changes.</td>
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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.
6/1/15  No policy statement changes.
6/1/16  No policy statement changes.
6/1/17  No policy statement changes. Added the word “Stent” to the title and changed to: Endovascular Stent Grafts for Abdominal Aortic Aneurysms.

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