Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Endovascular Stent Grafts for Disorders of the Thoracic Aorta is addressed separately in medical policy 00181.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider endoprostheses as a treatment of abdominal aortic aneurysms (AAAs) to be **eligible for coverage**.

Patient Selection Criteria
Coverage eligibility for the use of endoprostheses will be considered when all of the following criteria are met:

- The device is U.S. Food and Drug Administration (FDA) approved for the treatment of AAAs and is used according to the U.S. FDA labeling.
- As a treatment of AAAs in any of the following clinical situations:
    - An aneurysmal diameter greater than 5cm; or
    - An aneurysmal diameter of 4-5cm that has increased in size by 0.5cm in the last 6 months; or
    - An aneurysmal diameter that measures twice the size of the normal infrarenal aorta; or
    - A ruptured AAA (see Policy Guidelines section).

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of endoprostheses approved by the U.S. FDA as a treatment of AAAs is considered **investigational*,** 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.

The use of endoprostheses when patient selection criteria are not met is considered **investigational.***

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 06/20/2018

Policy Guidelines

For treatment of ruptured AAAs with endoprostheses, several factors must be considered including the following:

- The patient must be sufficiently stable to undergo detailed computed tomography (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 CT or ultrasonography every 6 to 12 months, or more frequently if perivascular leaks or aneurysm enlargement is detected.

Background/Overview

Conventional management of a clinically significant AAA consists of surgical excision with placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate between 1% and 5%. Perioperative morbidity and mortality are highest in older female patients with cardiac, pulmonary, or kidney disease; the most common cause of death is multisystem organ failure. Due to the high mortality rate, endovascular prostheses have been developed as a minimally invasive, catheter-based alternative to open surgical excision of AAAs. These devices are deployed across the aneurysm such that the aneurysm is effectively "excluded" from the circulation, with subsequent restoration of normal blood flow.

Several types of grafts are currently in use: 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. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A large number of endovascular grafts have been approved by the U.S. FDA through the premarket approval (PMA) process for treatment of AAAs (see Table 1). The original PMA dates are shown. Most stents have undergone device modification, name changes, and have approved supplements to the original PMA. FDA product code MIH.

Table 1. Abdominal Aortic Stent Grafts Approved by FDA

Stent Name	PMA Applicant	Approval Date	PMA No.
AneuRx® Prosthesis System (AneuRx AAAdvantage Stent Graft)	Medtronic Vascular	1999	P990020
Ancure® Aortoiliac System	Guidant Endovascular	2002	P990017

	Technologies		
Gore® Excluder®	W.L. Gore & Associates	2002	P020004
Zenith® AAA Endovascular Graft	Cook	2003	P020018
Endologix Powerlink® (Afx Endovascular AAA system)	Endologix	2004	P040002
Talent® Abdominal Stent Graft System	Medtronic	2008	P070027
Endurant® II AAA Stent Graft System	Medtronic	2010	P100021
Ovation™ Abdominal Stent Graft System	TriVascular	2012	P120006
Aorfix™ AAA Flexible Stent Graft System	Lombard Medical	2013	P110032

PMA: premarket approval.

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

Rationale/Source

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

The use of endovascular grafts also has potential disadvantages. In particular, there are concerns about 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.

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 compared 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 have demonstrated that the perioperative morbidity and mortality of an endovascular approach were reduced compared with open surgical repair. These results are consistent with large observational studies. However, the midterm results of these studies have suggested that the short-term improvements are not associated with a long-term benefit compared with an open approach.

Systematic Reviews
A 2014 Cochrane review assessed the evidence on the effectiveness of EVAR compared with open surgery for patients considered fit for surgery. Reviewers identified 4 trials considered high quality that compared EVAR with open repair (OVER, DREAM, EVAR 1, ACE; 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% confidence interval [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.

A 2017 individual patient data meta-analysis by Powell et al evaluated longer term outcomes from the 4 combined RCTs included in the 2014 Cochrane review (OVER, DREAM, EVAR-1, ACE), which are detailed below. The meta-analysis included 2783 patients with a median follow-up of 5.5 years. Mortality within 6 months of randomization was lower in the EVAR group, which was due primarily to a reduction in 30-day mortality (see Table 2). Beyond 3 years, aneurysm-related mortality was significantly higher in the EVAR group, resulting in a loss of survival benefit.

Table 2. Mortality Following EVAR or Open Repair in the Individual Patient Data Meta-Analysis of the OVER, DREAM, EVAR 1, and ACE Trials

Time of Follow-Up	EVAR n/N (%)	Open n/N (%)	HR	95% CI	p
Cumulative total deaths					
0-30 days	16/1373 (1.2%)	40/1351 (3.0%)	0.40	0.22 to 0.74	
0-6 months	46/1393 (3.3%)	73/1397 (5.5)%	0.61	0.42 to 0.89	<0.05
6 months to 4 years	244/1345 (18.1%)	229/1315 (17.4%)	1.04	0.87 to 1.25	*NS*
>4 years	191/987 (19.4%)	180/958 (26.4%)	1.07	0.88 to 1.32	*NS*
Aneurysm-related deaths					
0-30 days	16/1373 (1.2%)	40/1351 (3.0%)	0.41	0.22 to 0.74	<0.05
31 days to 3 years	18/1357 (1.3%)	33/1311 (2.5%)	1.07	0.49 to 2.36	*NS*
After 3 years	19/1118 (1.7%)	3/1054 (0.3%)	5.16	1.49 to 17.89	0.01

CI: confidence interval; EVAR: endovascular aneurysm repair; HR: hazard ratio.

Numerous nonrandomized studies have been performed, including the studies originally used as the basis for U.S. FDA approval. A systematic review of nonrandomized studies that compared EVAR with 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 who had open repair. Results of pooled analysis revealed that operative mortality was lower in the EVAR group (2.3%) than in 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 (relative risk, 1.10; 95% CI, 0.77 to 1.57).

Randomized Controlled Trials

The major RCTs that were included in the patient-level meta-analysis described above are OVER, DREAM, EVAR 1, and ACE. These are detailed next.

Open vs 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 or to open repair and followed 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 rates were similar between groups (hazard ratio [HR], 0.97; 95% CI, 0.77 to 1.22; p=0.81). On subgroup analysis, differences

in mortality rates were noted by 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 endovascular or to 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, 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 trialists suggested 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.

Longer term follow-up from this trial was reported in 2010. After 6 years of follow-up, survival rates were similar between the EVAR (68.9%) and the open repair (69.9%) groups (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%; 95% CI, 2.0 to 21.0; p=0.03).

Endovascular Aneurysm Repair vs Open Repair in Patients With Abdominal Aortic Aneurysm Trial
A larger trial, the 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 elective open or to endovascular repair. Similar to the DREAM trial, endovascular repair was associated with an improvement in aneurysm-related survival (4.7% open vs 1.7% endovascular 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.

Longer term follow-up from this trial was reported by the EVAR investigators in 2010. This follow-up included 1252 patients with aneurysms 5.5 cm or larger randomized to EVAR or to 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 has suggested that the early survival advantage of EVAR was lost over time due to late endograft ruptures, some of which were fatal.

Another follow-up from the EVAR 1 trial focused on cardiovascular morbidity and mortality at 5 years posttreatment. The EVAR group had a lower total cardiovascular event rate at all follow-up time points, but the difference during the trial 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 during the trial was similar between 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 at low-to-moderate surgical risk. A total of 306 patients were randomized from 25 clinical centers in France. Selection 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 (11%) crossovers from open surgery to EVAR and 4 (3%) crossovers from EVAR to open surgery. 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 with EVAR (16%) than with open surgery (2.7%; p<0.001). Endoleaks were identified on follow-up 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 comparing EVAR with open repair in 79,932 Medicare patients. Matching was based on demographic and clinical variables available for the 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 the 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.

Section Summary: Endovascular Aneurysm Repair as an Alternative to Open Repair for Treatment of AAAs
Evidence from several RCTs and meta-analyses of the RCTs supports EVAR as a reasonable alternative to open surgical repair for aneurysms greater than 5.5 cm, and 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 for EVAR and open surgery at 5 to 8 years of follow-up. For patients at low risk for open surgery, 1 RCT has

reported low perioperative morbidity and mortality rates for both EVAR and open surgery, with no differences 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 for ruptured AAAs is being studied as a treatment option 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 derived from nonrandomized studies comparing EVAR with 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, 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 who met eligibility for EVAR with those who did not. In a study by Krenzien et al (2013), those who were suitable for EVAR had a significantly lower prevalence of in-hospital deaths (25%) compared with patients unsuitable for EVAR (53%; p=0.02). In contrast, in a 2014 observational cohort of 279 patients who underwent open repair of suspected ruptured AAAs 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 these criteria (30%; p=0.23). Because of the possibility of selection bias, several nonrandomized studies have used patient matching or other methods to reduce potential for selection bias.

Two RCTs, published in 2013 and 2014, have compared short-term results following endovascular with open repair for ruptured aneurysms. One-year follow-up from the Immediate Management of Patients with Rupture: Open Versus Endovascular Repair (IMPROVE) trial (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.

Systematic Reviews

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 below). 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 findings 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 updated Cochrane review, Badger et al reviewed RCTs comparing emergency EVAR with surgical repair for clinically or radiologically diagnosed ruptured AAAs. Reviewers included 3 RCTs (n=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 trial did not adequately report random sequence generation, putting it at risk of selection bias, 2 studies did not report on outcomes identified in their protocols, 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).

Randomized Controlled Trials

Immediate Management of Patients With Rupture: Open vs Endovascular Repair Trial

The IMPROVE trial 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 emergency EVAR, with open repair for patients anatomically unsuitable for EVAR (endovascular strategy group), or to the standard treatment of emergency open repair (open repair group). Patients were excluded if they had had an aneurysm repair, rupture of an isolated internal iliac aneurysm, aorto-caval or aorto-enteric fistulae, recent anatomic assessment of the aorta (e.g., awaiting elective EVAR), a diagnosis of connective tissue disorder, or if the intervention was considered futile. The trial protocol permitted inclusion of hemodynamically unstable patients. Ten randomized patients 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. In the open repair randomization group, open repair was attempted in 220 (80%) patients, EVAR was attempted in 36 (13%) patients, and 19 patients died before repair.

For the trial'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 between groups for overall 30-day mortality (adjusted odds ratio [AOR], 0.94; 95% CI, 0.67 to 1.33; p=0.73). Compared with men (AOR=0.44), women demonstrated a greater benefit from EVAR (AOR=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).

One-year outcomes were reported in 2015. For the trial's primary 1-year outcome, survival data were available for 611 of 613 patients randomized. All-cause mortality did not differ significantly between the EVAR (41.1%) and the open repair groups (45.1%; OR=0.85; 95% CI, 0.62 to 1.17; p=0.325), with similar reintervention rates in both groups. 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 (MD) 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. The EuroQoL outcome difference exceeded the minimally clinically important difference of 0.03.

Amsterdam Acute Aneurysm Trial

In 2013, Reimerink et al reported on results from the Amsterdam Acute Aneurysm (AAA) trial, a regional multicenter randomized trial that compared EVAR with open repair in the treatment of ruptured AAA. 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 EVAR or to 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 for 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 them were excluded (16 were considered unfit for open repair, 11 for "logistics," 7 with severe hemodynamic instability after CTA, 5 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 during surgery and 4 perioperative deaths.

For the trial's primary outcome, rates of a composite end point (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 intensive care unit admission. The trialists 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 Chirgurgie dan les Aneuvysmes aorto-iliaques Rompus

In 2015, Desgranges et al reported on the 30-day and 1-year results of the multicenter Endovasculaire ou Chirgurgie dan les Aneuvysmes aorto-iliaques Rompus (ECAR) pseudo-randomized trial. 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, trial enrollment 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 the 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%, p=0.296), although the trial was underpowered to detect a difference of this magnitude.

The lower than expected mortality rate in the open repair group may have been due to the exclusion of patients with hemodynamic instability or unfavorable anatomic criteria. Despite 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
In 2014, Edwards et al published an evaluation of outcomes after EVAR and 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 included 1099 patient pairs who were propensity-score matched based for baseline demographics, comorbid conditions, admission source, and hospital volume of ruptured AAA repair. Short-term mortality was significantly lower in the EVAR group (33.8% vs 47.7%, p<0.001). The survival benefit persisted until 4 years postsurgery. However, at 36 months after 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 trial included its 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 trial was subject to bias because unobserved variables might have been associated with the decision to perform open repair.

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 rates for EVAR did not differ significantly from those for open surgery. Longer term outcomes comparing EVAR with open surgery for ruptured aneurysms have not been reported.

EVAR VS NONSURGICAL TREATMENT FOR SMALLER ANEURYSMS NOT MEETING CURRENT SIZE CRITERIA FOR SURGERY OR FOR PATIENTS INELIGIBLE FOR OPEN SURGERY
Few randomized trials have addressed patients with aneurysms that cannot be treated by open surgery. This population includes patients with smaller aneurysms that do not meet the size threshold for open surgery and patients who cannot undergo open surgery due to prohibitive operative risk.

EVAR for Smaller Aneurysms
Systematic Reviews
A 2012 Cochrane Review summarized the evidence on interventions for small aneurysms, 4.0 to 5.5 cm in size, either by open surgery or EVAR. Four RCTs were identified, including 2 RCTs on EVAR (discussed below) 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 4 trials were combined.

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. 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. Patients were assessed with the 36-Item Short-Form Health Survey (SF-36) 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 SF-36 overall score (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 did not differ significantly at 1 year and beyond.

The PIVOTAL (Positive Impact of Endovascular Options for Treating Aneurysms Early) trial randomized 728 patients with AAAs of 4 to 5 cm to early EVAR or to ultrasound surveillance. 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 (4.1%). Aneurysm rupture or aneurysm-related death occurred at a low rate and was also the same for both groups (0.6%). The HR for the primary outcome measures was 0.99 (95% CI, 0.14 to 7.06).

EVAR for Patients at Prohibitive Surgical Risk

A single 2005 RCT has compared endovascular repair for AAAs with no surgical intervention in patients 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. EVAR 2 randomized 338 patients to 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 were 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 for this trial was reported in 2010 on 404 patients randomized to EVAR or to 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 2006 Agency for Healthcare Research and Quality (AHRQ) report comparing endovascular with open surgical repair for AAA concluded that endovascular repair does not improve survival in patients who are medically unfit for open surgery. As previously discussed, the EVAR 2 trial, and thus the AHRQ assessment, was 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 (2006), based on both randomized and nonrandomized trials, have suggested that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open surgeries.

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 reviewers' 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 (2015) retrospectively compared outcomes after EVAR for 75 patients considered high risk based on 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 would suggest that EVAR may be feasible with reasonable outcomes in patients at high medical risk, but conclusions that might be drawn from this study are limited by its retrospective nature.

Section Summary: EVAR vs 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 has suggested that morbidity and mortality outcomes from surveillance are as good as those from early intervention with EVAR. For patients 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 biased by a high rate of crossovers, primarily from open surgery to EVAR, which would limit the ability to detect a difference between the 2 treatments.

SUMMARY OF EVIDENCE

For individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of 4 RCTs comparing EVAR with open repair for elective treatment of AAAs has indicated that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in mortality, outcomes at 5 years or longer have shown a greater endovascular mortality and comparable overall 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. 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 that the technology results in a meaningful improvement in the net health outcome.

For 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 mortality and morbidity. For patients with ruptured AAAs, evidence from 4 RCTs and a patient-level meta-analysis has indicated 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have AAAs ineligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. 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 that the technology is unlikely to improve the net health outcome.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Endovascular Stent Grafts for Abdominal Aortic Aneurysms”, 7.01.67, 5:2017.
2. Blue Cross and Blue Shield Association. Endovascular Stent-Grafts for Abdominal Aortic Aneurysm Repair. TEC Assessment Program. 2001;16(2).
3. Blum U, Voshage G, Lammer J, et al. Endoluminal stent-grafts for infrarenal abdominal aortic aneurysms. N Engl J Med. Jan 2 1997;336(1):13-20. PMID 8970935
4. Ernst CB. Current therapy for infrarenal aortic aneurysms. N Engl J Med. Jan 2 1997;336(1):59-60. PMID 8970942
5. White RA, Donayre CE, Walot I, et al. Modular bifurcation endoprosthesis for treatment of abdominal aortic aneurysms. Ann Surg. Sep 1997;226(3):381-389; discussion 389-391. PMID 9339944
6. Zarins CK, White RA, Schwarten D, et al. AneuRx stent graft versus open surgical repair of abdominal aortic aneurysms: multicenter prospective clinical trial. J Vasc Surg. Feb 1999;29(2):292-305; discussion 306-298. PMID 9950987
7. Greenlagh R, Brown IC, Epstein D, et al. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. Lancet. Jun 25-Jul 1 2005;365(9478):2179-2186. PMID 15978925
8. Blankensteijn JD, de Jong SE, Prinssen M, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. N Engl J Med. Jun 9 2005;352(23):2398-2405. PMID 15944424

9. Greenlagh R, Brown IC, Epstein D, et al. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomised controlled trial. Lancet. Jun 25-Jul 1 2005;365(9478):2187-2192. PMID 15978926
10. Greenhalgh RM, Brown LC, Kwong GP, et al. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. Lancet. Sep 4-10 2004;364(9437):843-848. PMID 15351191
11. Prinssen M, Verhoeven EL, Buth J, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. N Engl J Med. Oct 14 2004;351(16):1607-1618. PMID 15483279
12. Anderson PL, Arons RR, Moskowitz AJ, et al. A statewide experience with endovascular abdominal aortic aneurysm repair: rapid diffusion with excellent early results. J Vasc Surg. Jan 2004;39(1):10-19. PMID 14718804
13. Hua HT, Cambria RP, Chuang SK, et al. Early outcomes of endovascular versus open abdominal aortic aneurysm repair in the National Surgical Quality Improvement Program-Private Sector (NSQIP-PS). J Vasc Surg. Mar 2005;41(3):382-389. PMID 15838467
14. Lee WA, Carter JW, Upchurch G, et al. Perioperative outcomes after open and endovascular repair of intact abdominal aortic aneurysms in the United States during 2001. J Vasc Surg. Mar 2004;39(3):491-496. PMID 14981436
15. Paravastu SC, Jayarajasingam R, Cottam R, et al. Endovascular repair of abdominal aortic aneurysm. Cochrane Database Syst Rev. 2014;1:CD004178. PMID 24453068
16. Powell JT, Sweeting MJ, Ulug P, et al. Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years. Br J Surg. Feb 2017;104(3):166-178. PMID 28160528
17. Biancari F, Catania A, D'Andrea V. Elective endovascular vs. open repair for abdominal aortic aneurysm in patients aged 80 years and older: systematic review and meta-analysis. Eur J Vasc Endovasc Surg. Nov 2011;42(5):571-576. PMID 21820922
18. Lederle FA, Freischlag JA, Kyriakides TC, et al. Long-term comparison of endovascular and open repair of abdominal aortic aneurysm. N Engl J Med. Nov 22 2012;367(21):1988-1997. PMID 23171095
19. De Bruin JL, Baas AF, Buth J, et al. Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. N Engl J Med. May 20 2010;362(20):1881-1889. PMID 20484396
20. Greenhalgh RM, Brown LC, Powell JT, et al. Endovascular versus open repair of abdominal aortic aneurysm. N Engl J Med. May 20 2010;362(20):1863-1871. PMID 20382983
21. Brown LC, Thompson SG, Greenhalgh RM, et al. Incidence of cardiovascular events and death after open or endovascular repair of abdominal aortic aneurysm in the randomized EVAR trial 1. Br J Surg. Jul 2011;98(7):935-942. PMID 21484775
22. Becquemin JP, Pillet JC, Lescalie F, et al. A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients. J Vasc Surg. May 2011;53(5):1167-1173 e1161. PMID 21276681
23. Schermerhorn ML, Buck DB, O'Malley AJ, et al. Long-term outcomes of abdominal aortic aneurysm in the Medicare population. N Engl J Med. Jul 23 2015;373(4):328-338. PMID 26200979
24. Krenzien F, Matia I, Wiltberger G, et al. Outcome after open surgery repair in endovascular-suitable patients with ruptured abdominal aortic aneurysms. Vasa. Nov 2013;42(6):442-448. PMID 24220121
25. van Beek SC, Reimerink JJ, Vahl AC, et al. Outcomes after open repair for ruptured abdominal aortic aneurysms in patients with friendly versus hostile aortoiliac anatomy. Eur J Vasc Endovasc Surg. Apr 2014;47(4):380-387. PMID 24485844
26. Sweeting MJ, Balm R, Desgranges P, et al. Individual-patient meta-analysis of three randomized trials comparing endovascular versus open repair for ruptured abdominal aortic aneurysm. Br J Surg. Sep 2015;102(10):1229-1239. PMID 26104471
27. Badger S, Bedenis R, Blair PH, et al. Endovascular treatment for ruptured abdominal aortic aneurysm. Cochrane Database Syst Rev. 2014;7:CD005261. PMID 25042123
28. Improve Trial Investigators, Powell JT, Sweeting MJ, et al. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial. BMJ. 2014;348:f7661. PMID 24418950
29. Improve Trial Investigators. Endovascular strategy or open repair for ruptured abdominal aortic aneurysm: one-year outcomes from the IMPROVE randomized trial. Eur Heart J. Aug 14 2015;36(31):2061-2069. PMID 25855369
30. Reimerink JJ, Hoornweg LL, Vahl AC, et al. Endovascular repair versus open repair of ruptured abdominal aortic aneurysms: a multicenter randomized controlled trial. Ann Surg. Aug 2013;258(2):248-256. PMID 23549424
31. Desgranges P, Kobeiter H, Katsahian S, et al. ECAR (Endovasculaire ou Chirurgie dans les Anevrysmes aorto-iliaques Rompus): A French randomized controlled trial of endovascular versus open surgical repair of ruptured aorto-iliac aneurysms. Eur J Vasc Endovasc Surg. Sep 2015;50(3):303-310. PMID 26001320

32. Edwards ST, Schermerhorn ML, O'Malley AJ, et al. Comparative effectiveness of endovascular versus open repair of ruptured abdominal aortic aneurysm in the Medicare population. J Vasc Surg. Mar 2014;59(3):575-582. PMID 24342064
33. Filardo G, Powell JT, Martinez MA, et al. Surgery for small asymptomatic abdominal aortic aneurysms. Cochrane Database Syst Rev. 2012;3:CD001835. PMID 22419281
34. Cao P, De Rango P, Verzini F, et al. Comparison of surveillance versus aortic endografting for small aneurysm repair (CAESAR): results from a randomised trial. Eur J Vasc Endovasc Surg. Jan 2011;41(1):13-25. PMID 20869890
35. Ouriel K, Clair DG, Kent KC, et al. Endovascular repair compared with surveillance for patients with small abdominal aortic aneurysms. J Vasc Surg. May 2010;51(5):1081-1087. PMID 20304589
36. De Rango P, Verzini F, Parlani G, et al. Quality of life in patients with small abdominal aortic aneurysm: the effect of early endovascular repair versus surveillance in the CAESAR trial. Eur J Vasc Endovasc Surg. Mar 2011;41(3):324-331. PMID 21145269
37. Greenhalgh RM, Brown LC, Powell JT, et al. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. N Engl J Med. May 20 2010;362(20):1872-1880. PMID 20382982
38. Wilt TJ, Lederle FA, Macdonald R, et al. Comparison of endovascular and open surgical repairs for abdominal aortic aneurysm. Evid Rep Technol Assess (Full Rep). Aug 2006(144):1-113. PMID 17764213
39. Hirsch AT, Haskal ZJ, Hertzer NR, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): executive summary a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease) endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. J Am Coll Cardiol. Mar 21 2006;47(6):1239-1312. PMID 16545667
40. Lim S, Halandras PM, Park T, et al. Outcomes of endovascular abdominal aortic aneurysm repair in high-risk patients. J Vasc Surg. Apr 2015;61(4):862-868. PMID 25704411
41. Erbel R, Aboyans V, Boileau C, et al. 2014 ESC Guidelines on the diagnosis and treatment of aortic diseases: Document covering acute and chronic aortic diseases of the thoracic and abdominal aorta of the adult. The Task Force for the Diagnosis and Treatment of Aortic Diseases of the European Society of Cardiology (ESC). Eur Heart J. Nov 1 2014;35(41):2873-2926. PMID 25173340
42. Rooke TW, Hirsch AT, Misra S, et al. 2011 ACCF/AHA focused update of the guideline for the management of patients with peripheral artery disease (updating the 2005 guideline): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Nov 1 2011;58(19):2020-2045. PMID 21963765
43. 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 Society of Europe and the Canadian Interventional Radiology Association. J Vasc Interv Radiol. Nov 2010;21(11):1632-1655. PMID 20884242
44. Chaikof EL, Brewster DC, Dalman RL, et al. SVS practice guidelines for the care of patients with an abdominal aortic aneurysm: executive summary. J Vasc Surg. Oct 2009;50(4):880-896. PMID 19786241

Policy History

Original Effective Date: 01/27/2003
Current Effective Date: 06/20/2018

11/21/2002	Medical Policy Committee review
01/27/2003	Managed Care Advisory Council approval
01/20/2004	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged
01/31/2005	Managed Care Advisory Council approval
05/17/2005	Medical Policy Committee review. Format revision. Policy statement changed from

	endoprostheses (i.e., endovascular grafts) as a treatment of abdominal aortic aneurysms (infrarenal abdominal or aortoiliac aneurysms) to: the use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms. Patient selection criteria expanded to include; "The use of FDA-approved endoprostheses 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, consistent with the FDA-labeled indications for the AneurRx device." Investigational statement added to address non FDA-Approved devices and situations when patient selection criteria are not met.
05/23/2005	Managed Care Advisory Council approval
07/07/2006	Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/02/2006	Medical Director Review
08/09/2006	Medical Policy Committee approval. Rationale /Source and rationale updated.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Policy statement added for treatment of ruptured abdominal aortic aneurysm as investigational.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Changed coverage statement from investigational to eligible for coverage with criteria for ruptured abdominal aortic aneurysms.
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. For clarification, added that the use of endoprostheses approved by the U.S. FDA as a treatment of abdominal aortic aneurysms is considered investigational for certain clinical situations.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. No change to coverage.
03/04/2013	Coding revised
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Added "stent" to the title. Coverage eligibility unchanged.
01/01/2018	Coding update
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	34808, 34812, 34813, 34820, 34833, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848 Codes to be deleted eff 1/1/2018: 34800, 34802, 34803, 34804, 34805, 34806, 34825, 34826, 75952, 75953 Codes to be added eff 1/1/2018: 34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34714, 34715, 34716
HCPCS	No codes
ICD-10 Diagnosis	I71.02 I71.3 I71.4 I71.8

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.