7.01.67	Endovascular Stent Grafts for Abdominal Aortic Aneurysms		
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Section:	7.0 Surgery	**Page:**	Page 1 of 31

Policy Statement

I. The use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) as a treatment of abdominal aortic aneurysms (AAAs) may be considered **medically necessary** in **any** of the following clinical situations:
   A. A ruptured abdominal aortic aneurysm (see policy guidelines section)
   B. An aneurysmal diameter greater than 5.0 centimeters (cm)
   C. An aneurysmal diameter of 4 to 5.0 cm that has increased in size by 0.5 cm in the last 6 months
   D. An aneurysmal diameter that measures twice the size of the normal infrarenal aorta

II. The use of endoprostheses approved by the FDA as a treatment of AAAs is considered **investigational** when the above criteria are not met, including but not limited to, **either** of the following clinical situations:
   A. 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
   B. Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

For treatment of ruptured abdominal aortic aneurysms 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
- Specialized personnel should be available

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

Coding

The overall procedure involves 4 steps:

- Establishing vascular access
- Introducing catheters and guide wires into the arterial system
- Deploying the endoprosthesis
- Radiologic supervision

Step 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 (List separately in addition to code for primary procedure)

- **34820**: Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)

Step 2
The following CPT codes describe the introduction of catheters and guide wires:

- **36200**: Introduction of catheter, aorta

Sometimes the renal arteries are catheterized to ensure that they are not obstructed by the prosthesis. If this is the case, the following CPT code may be used:

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

Step 3
The following CPT codes describe the deployment of the prosthesis and ***will replace CPT codes 34800-34805 and 34825-34826***:

- **34701**: 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 (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
- **34702**: 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 rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
- **34703**: Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
- **34704**: Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
- **34705**: Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
- **34706**: Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)

- **34707**: 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 (e.g., 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 rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., 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)

Step 4
The following CPT code describes radiologic supervision and ***will replace CPT codes 75952-75953***, to report use 34701-34711 and 0254T:

- **0254T**: Endovascular repair of iliac artery bifurcation (e.g., aneurysm, pseudoaneurysm, arteriovenous malformation, trauma, dissection) using bifurcated endograft from the common iliac artery into both the external and internal iliac artery, including all selective and/or nonselective catheterization(s) required for device placement and all associated radiological supervision and interpretation, unilateral

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**: 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

There are also category I CPT codes for the use of fenestrated endografts to repair the visceral aorta (34841-34844) and the visceral aorta and infrarenal abdominal aorta (34845-34848):

- **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**: Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
- **34843**: Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
- **34844**: Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
- **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**: 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 two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
- **34847**: 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 three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
- **34848**: 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 four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

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.

Note: As experience with this technology matures, placement of endovascular stents as a treatment of AAAs may be performed by either an interventional radiologist or vascular surgeon in the outpatient setting.

Description

Endovascular stent grafts can be used as 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.

Related Policies

- Endovascular Stent Grafts for Disorders of the Thoracic Aorta

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

A large number of endovascular grafts have been approved by the U.S. Food and Drug Administration 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. Food and Drug Administration product code MIH.

Table 1. Abdominal Aortic Stent Grafts Approved by the FDA

Stent Name	PMA Applicant	Approved	PMA No.
AneuRx® Prosthesis System (AneuRx AAAdvantage Stent Graft)	Medtronic Vascular	1999	P990020
Ancure® Aortoiliac System	Guidant Endovascular Technologies	2002	P990017
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
Valiant Thoracic Stent Graft System	Medtronic	2011	P100040
Relay Thoracic Stent-Graft with Plus Delivery System	Bolton Medical	2012	P110038
Ovation™ Abdominal Stent Graft System	TriVascular	2012	P120006
Aorfix™ AAA Flexible Stent Graft System	Lombard Medical	2013	P110032

FDA: Food and Drug Administration; PMA: premarket approval.

Rationale

Background

Conventional management of a clinically significant abdominal aortic aneurysm (AAA) consists of surgical excision with the 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 less risky and 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.

The main potential advantage of endovascular grafts for an AAA is that they offer a less invasive and less risky approach to the repair of abdominal aneurysms. While the use of an endovascular 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 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.[1-4,]

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. Also, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Endovascular Stent Grafts as an Alternative to Open Repair for Elective Treatment of Abdominal Aortic Aneurysm

Clinical Context and Therapy Purpose

The purpose of endovascular stent grafts is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as open repair, in patients with abdominal aortic aneurysm (AAA) who are candidates for elective surgical repair.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with AAA eligible for open repair.

Interventions

The therapy being considered is endovascular stent grafts. Endovascular stent grafts can be used as minimally invasive alternatives to open surgical repair for the treatment of 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.

Comparators

Comparators of interest include open surgical repair.

Outcomes

The general outcomes of interest are overall survival (OS), morbid events, treatment-related morbidity, and treatment-related mortality (Table 2). Follow-up of at least 5 years is desirable to assess outcomes.

Table 2. Outcomes of Interest for Individuals with AAA Eligible for EVAR or Open Repair

Outcomes	Details	Timing
Overall survival	Survival following EVAR or open repair	≥1 year
Morbid events	Adverse events or necessary reinterventions following EVAR or open repair	≥1 year
Treatment-related mortality	Cause of death related to aneurysm or other cardiac event following EVAR or open repair	≥1 year
Treatment-related morbidity	Adverse events or necessary reinterventions related to aneurysm or other cardiac event following EVAR or open repair	≥1 year

AAA: abdominal aortic aneurysm; EVAR: endovascular aneurysm repair

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

A number of moderate- to large-sized RCTs have compared EVAR with open surgical repair, and these studies comprise the main body of literature on the comparative efficacy of the 2 procedures.[6,7,8] 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.[9,10] These results are consistent with large observational studies.[11,12,13] However, the mid- and long-term results of these studies are consistent in finding that the short-term improvements are not associated with a long-term benefit compared with an open approach.

Systematic Reviews

Several systematic reviews have been published comparing EVAR to open repair of AAA. Two, Paravastu et al (2014) and Powell et al (2017), focused solely on the 4 RCTs described later in this section.[14,15] A few other systematic reviews included other studies in their analyses.[16,17,18,19,20,21]
Li et al (2019) was the largest of the systematic reviews.[20] This meta-analysis included 73 studies (N=299,784) that compared EVAR (n=151,092) and open repair (n=148,692) outcomes for long-term (5 to 9 y) and very long-term (≥10 y) all-cause mortality, reintervention, and secondary rupture rates. The study years ranged from 1999 to 2018 and included 3 RCTs (5 articles) and 68 observational studies. Follow-up ranged from 5 to 15 years. Results are summarized in Table 3. Endovascular aneurysm repair was associated with higher long-term all-cause mortality, reintervention, and secondary rupture rates compared with open surgical repair. In the very long-term, EVAR was also associated with higher reintervention and secondary rupture rates but mortality rates were seen to improve over time.

Table 3. Long-Term and Very Long-Term Outcomes of EVAR Versus Open Repair

	All-Cause Mortality		Reintervention		Secondary Rupture	
Length of follow-up	5-9 y	≥10 y	5-9 y	≥10 y	5-9 y	≥10 y (1 study)
EVAR	27.3%	NR	17.6%	20.9%	2.0%	NR
OSR	24.7%	NR	14.9%	12.3%	0.6%	NR
OR	1.19	0.92	2.12	2.47	4.84	8.10
95% CI	1.06-1.33	0.76-1.11	1.67-2.69	1.71-3.57	2.63-8.89	1.01-64.99
p-value	.003	.39	<.001	<.001	<.001	.05
I^2	91%	89%	96%	84%	92%	NA

Source: Li et al (2019).[20]
CI: confidence interval; EVAR: endovascular aneurysm repair; NA: not applicable; NR: not reported; OR: odds ratio; OSR: open surgical repair; y: year(s).

Paravastu et al (2014) published a Cochrane review assessing the evidence on the effectiveness of EVAR compared with open surgery for patients considered fit for surgery.[14] Reviewers identified 4 trials considered high-quality that compared EVAR with open repair (Open Versus Endovascular Repair [OVER], Dutch Randomized Endovascular Aneurysm Repair [DREAM], Endovascular Aneurysm Repair Versus Open Repair in Patients With Abdominal Aortic Aneurysm [EVAR 1], Anévrisme de l'aorte abdominale: Chirurgie versus Endoprothese[ACE]; N=2790). 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 <.001). There were no significant differences in mortality between EVAR and open repair groups at intermediate-term follow-up.

Powell et al (2017) published an individual patient data meta-analysis evaluating longer-term outcomes from the 4 combined RCTs included in the 2014 Cochrane review (OVER, DREAM, EVAR-1, ACE).[15] 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 (Table 4). Beyond 3 years, aneurysm-related mortality was significantly higher in the EVAR group, resulting in a loss of survival benefit.

Table 4. Mortality After EVAR or Open Repair in the OVER, DREAM, EVAR 1, and ACE Trials

Morbidity by Time of Follow-Up	EVAR n/N (%)	Open n/N (%)	HR	95% CI	p-value
Cumulative total deaths					
0-30 days	16/1373 (1.2)	40/1351 (3.0)	0.40	0.22-0.74	NR
0-6 months	46/1393 (3.3)	73/1397 (5.5)	0.61	0.42-0.89	<.05
6 months to 4 years	244/1345 (18.1)	229/1315 (17.4)	1.04	0.87-1.25	NS
> 4 years	191/987 (19.4)	180/958 (26.4)	1.07	0.88-1.32	NS
Aneurysm-related deaths					
0-30 days	16/1373 (1.2)	40/1351 (3.0)	0.41	0.22-0.74	<.05
31 days to 3 years	18/1357 (1.3)	33/1311 (2.5)	1.07	0.49-2.36	NS
> 3 years	19/1118 (1.7)	3/1054 (0.3)	5.16	1.49-17.89	.01

Adapted from Powell et al (2017).[15,]

ACE: Anévrisme de l'aorte abdominale: Chirurgie versus Endoprothese; CI: confidence interval; DREAM: Dutch Randomized Endovascular Aneurysm Repair; EVAR: endovascular aneurysm repair; EVAR 1: Endovascular Aneurysm Repair Versus Open Repair in Patients With Abdominal Aortic Aneurysm; HR: hazard ratio; NR: not reported; NS: not significant; OVER: Open Versus Endovascular Repair.

Yokoyama et al (2020) published a meta-analysis evaluating longer-term outcomes from the 4 key RCTs included in previous meta-analyses (OVER, DREAM, EVAR-1, ACE) plus 7 propensity-matched cohort studies (N=106,243); one of the included cohort studies (Salata et al [2019]) had not previously been included in a pooled analysis.[21,] Overall, EVAR reduced mortality versus open surgical repair (OSR) during the perioperative period, but increased mortality versus OSR during the post-operative periods that included 1 to 24 months and 2 to 6 years after repair (Table 5). There were no significant differences in mortality between groups when evaluating the following postoperative periods: 0 to 2 years, 6 to 10 years, and ≥10 years.

Table 5. Mortality after EVAR versus Open Repair

Morbidity by Time of Follow-Up	HR	95% CI	P-value
Perioperative (≤1 month)	0.39	0.29-0.51	<.00001
1 to 24 months*	1.15	1.11-1.19	<.0001
0 to 2 years	0.93	0.84-1.03	.16
2 to 6 years	1.15	1.03-1.29	.01
6 to 10 years	1.06	0.96-1.17	.27
≥10 years	1.17	0.93-1.47	.19

Adapted from Yokoyama et al (2020).[21,]

*Analysis for mortality between 1 month and 24 months after repair was performed to exclude the effect of perioperative mortality on the early-term mortality.
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. Food and Drug Administration (FDA) approval. Biancari et al (2011) published a systematic review of nonrandomized studies that compared EVAR with open surgery in elderly patients, 80 years or older.[22,] 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 the pooled analysis revealed that immediate postprocedure 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).

Ulug et al (2017) published a systematic review of 5 studies of men and women who underwent intact AAA repair, either through open repair or EVAR.[23,] Three separate meta-analyses were conducted to address 3 issue areas. One meta-analysis included 5 studies and compared morphologic eligibility for EVAR between men and women. There was a greater likelihood that men were deemed eligible for EVAR, (OR, 0.44; 95% CI, 0.32 to 0.63). Another meta-analysis assessed the likelihood of nonintervention in women compared with men. Four studies were included (1365 men, 247 women), and the likelihood of nonintervention in women was 34% vs. 19% in men (OR, 2.27; 95% CI, 1.21 to 4.23).

The third meta-analysis included 9 studies (52018 men, 11076 women) and evaluated the 30-day mortality rate after EVAR. The 30-day mortality rate for women was 2.3% and 1.4% for men (OR, 1.67; 95% CI, 1.38 to 2.04). Reviewers noted that their analysis was limited by inconsistent reporting of confounders such as age, aneurysm diameter, and comorbidities. Overall, fewer women were offered EVAR than men, and, for both EVAR and open repair, women had a higher incidence of mortality following the procedure.

Antoniou (2021) published a meta-analysis comparing outcomes of fenestrated or branched EVAR with open repair for juxta/para/suprarenal or thoraco-AAAs.[17] Eleven observational studies were included (N=7061). Fenestrated or branched EVAR did not significantly lower peri-operative mortality (OR, 0.56; 95% CI, 0.28 to 1.12; p=.10) or increase overall mortality (hazard ratio [HR], 1.25; 95% CI, 0.93 to 1.67; p=.14) versus open repair. However, reintervention was significantly more likely after EVAR (HR, 2.11; 95% CI 1.39 to 3.18; p<.001).

Randomized Controlled Trials

The major RCTs included in the patient-level meta-analyses described above are OVER, DREAM, EVAR 1, and ACE. These trials are discussed below.

Open Versus Endovascular Repair Trial

Lederle et al (2012) published long-term results of the OVER trial.[24] 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 (up to 3 years) was reported for EVAR, but at final follow-up, mortality rates were similar between groups (HR, 0.97; 95% CI, 0.77 to 1.22; p=.81). In 1 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).

Lederle et al (2019) reported on the 14-year extended follow-up for the OVER trial.[25] The primary outcome was all-cause mortality. Of the 444 patients assigned to EVAR, 302 (68.0%) had died, and of the 437 open-repair patients, 306 (70.0%) had died (HR, 0.96; 95% CI, 0.82 to 1.13; p=.61). Deaths associated with AAA were seen in 12 (2.7%) EVAR patients and 16 (3.7%) open repair (95% CI, -3.3 to 1.4). Of those deaths, 2 EVAR patients died either during hospitalization or within 30 days after repair; 11 open-repair patients died during that same period. Of the EVAR group, 117 out of 439 (26.7%) patients underwent a secondary procedure compared with 85 of 429 (19.8%) patients in the open repair group (95% CI, 2.0 to 17.5). During the first 4 years of follow-up, OS appeared to be higher with endovascular repair than with open repair; from year 4 through year 8, OS was higher in the open-repair group; and after 8 years, OS was once again higher in the endovascular-repair group (HR for death, 0.94; 95% CI, 0.74 to 1.18). None of these trends were significant.

Dutch Randomized Endovascular Aneurysm Management Trial

The DREAM trial enrolled 351 patients who were randomized to endovascular or open repair.[8] The incidence of aneurysm-related death (ie, within 30 days) was 4.6% in the open repair group and 1.2% in the endovascular repair group. However, after 2 years, 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 investigators 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.

De Bruin et al (2010) reported on longer-term follow-up from the DREAM trial.[26] 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=.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=.03).

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

Greenhalgh et al (2005) reported on a larger trial, the EVAR 1, which enrolled 1082 patients 60 years or older with abdominal aneurysms at least 5.5 cm in diameter and randomized them to elective open repair or to endovascular repair.[7] 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, the endoscopic repair was associated with a complication rate of 41% compared with only 9% in the surgically treated group.

Greenhalgh et al (2010) also reported on longer-term follow-up from EVAR 1.[27] 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 would suggest that the early survival advantage of EVAR was lost over time due to late endograft ruptures, some of which were fatal.

Brown et al (2011) reported on follow-up from the EVAR 1 trial as well, focusing on cardiovascular morbidity and mortality at 5 years posttreatment.[28] The EVAR group had a lower total cardiovascular event rate at all follow-up time points, but differences during the trial were 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 a 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).

Anévrisme de l'aorte abdominale: Chirurgie Versus Endoprothese Trial

The ACE trial compared EVAR with open surgical repair in patients at low-to-moderate surgical risk.[29] 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 crossovers from open surgery to EVAR (11%) and 4 crossovers from EVAR to open surgery (3%). The median follow-up was 3 years.

The perioperative mortality rate was 1.3% for the EVAR group and 0.6% for the open surgery group (p=.12). The survival rate at 1 year was 95.2% for EVAR and 96.5% for open surgery (p=.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 patients, a difference that was also not statistically significant. Reinterventions were more common with EVAR (16%) than with open surgery (2.7%; p<.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.

Section Summary: Endovascular Stent Grafts as an Alternative to Open Repair for Treatment of Abdominal Aortic Aneurysm

Evidence from several RCTs and meta-analyses of RCTs and cohort studies has supported 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 who are appropriate candidates 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 reintervention. Longer-term mortality is generally similar for EVAR and open surgery at 6 or more years of follow-up. For patients at low to moderate 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 to moderate risk for surgery.

Endovascular Aneurysm Repair as an Alternative to Open Repair for Ruptured Abdominal Aortic Aneurysm

Clinical Context and Therapy Purpose

The purpose of endovascular stent grafts is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as open repair, in patients with ruptured AAA.
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with ruptured AAA.

Interventions

The therapy being considered is endovascular stent grafts. Endovascular stent grafts can be used as minimally invasive alternatives to open surgical repair for treatment of 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.

Comparators

Comparators of interest include open repair.

Outcomes

The general outcomes of interest are OS, morbid events, treatment-related morbidity, and treatment-related mortality (Table 6).

Follow-up of at least 5 years is desirable to assess outcomes.

Table 6. Outcomes of Interest for Individuals with Ruptured AAA Eligible for EVAR or Open Repair

Outcomes	Details	Timing
Overall survival	Survival following EVAR or open repair for ruptured AAA	≥1 year
Morbid events	Adverse events or necessary reinterventions following EVAR or open repair for ruptured AAA	≥1 year
Treatment-related mortality	Cause of death related to aneurysm or other cardiac event following EVAR or open repair for ruptured AAA	≥1 year
Treatment-related morbidity	Adverse events or necessary reinterventions related to aneurysm or other cardiac event following EVAR or open repair for ruptured AAA	≥1 year

AAA: abdominal aortic aneurysm; EVAR: endovascular aneurysm repair.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Emergency EVAR for ruptured AAAs is being studied as a treatment option to decrease the high mortality rate associated with open surgical repair. Conducting RCTs has been difficult in this patient population 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 was derived from nonrandomized studies comparing EVAR with open surgery. However, there is a high risk of 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 EVAR by comparing outcomes for patients who underwent open repair who met eligibility for EVAR with those who did not. Krenzien et al (2013) found that those suitable for EVAR had a significantly lower prevalence of in-hospital deaths (25%) than those unsuitable for EVAR (53%; p=.02).[30] Van Beek et al (2014), in contrast, reported an 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).[31] They found that 30-day morbidity was not lower among the 71 patients who met the criteria for EVAR (38%) compared with the 208 patients who did not (30%; p=.23). Several nonrandomized studies have used patient matching or other methods to reduce the potential for selection bias.

Systematic Reviews

Sweeting et al (2015) published a patient-level meta-analysis of 3 RCTs (N=836) that compared EVAR with open repair for ruptured AAAs.[32] To have a more uniform comparison, 90-day data from only the patients who were anatomically suitable for EVAR who participated in the Immediate Management of Patients With Rupture: Open Versus Endovascular Repair Trial (IMPROVE) were analyzed along with patient-level data from the Amsterdam Acute Aneurysm Trial (AJAX) and Endovasculaire ou Chirurgie Dans Les Anévrismes Aorto-Iliaques Rompus (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 (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).

Badger et al (2017) published the most recent relevant Cochrane review, reporting on 4 RCTs (AJAX, ECAR, Hinchliffe et al [2006], and IMPROVE), which evaluated short- and mid-term outcomes of 868 patients with ruptured AAA treated with emergency EVAR or open repair.[33] For the primary outcome, short-term mortality (defined as 30-day or in-hospital mortality), there was no significant difference between EVAR and open repair (OR, 0.88; 95% CI, 0.66 to 1.16; p=.36). Secondary outcomes (endoleak events, 30-day complication rates, 6-month mortality) were not assessed in all studies. Reductions in bowel ischemia (a secondary outcome) were more significant in the EVAR group than in the open repair group (OR, 0.37; 95% CI, 0.14 to 0.94; p=.04). Using data from the AJAX trial (n=116), reviewers found no 6-month survival advantage for patients treated with emergency EVAR (OR, 0.89; 95% CI, 0.40 to 1.98).

An individual patient-level meta-analysis of similar design to the analysis by Sweeting et al (2015) included long-term follow-up data from the IMPROVE, AJAX, and ECAR trials (N=725) as well as non-RCTs with greater than 30-day follow-up comparing EVAR and open repair in patients with ruptured AAA (N=12,187, including the patients from the 3 RCTs).[34] In the full pooled time-to-event analysis with post-intervention follow-up of up to 10 years, the authors found that life expectancy was approximately 6.5 months longer in patients who underwent EVAR versus open repair. As in the earlier meta-analysis, sensitivity analysis restricted to data from IMPROVE, AJAX, and ECAR (up to 6 years' follow-up) did not indicate a difference in mortality.

Randomized Controlled Trials

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

The IMPROVE trial randomized 613 patients at 30 centers (29 in the UK, 1 in Canada) with a clinical diagnosis of a ruptured AAA to an endovascular strategy of immediate CT and emergency EVAR (n=316), or to the standard treatment of emergency open repair (n=297).[35] 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 (eg, awaiting elective EVAR), a diagnosis of connective tissue disorder, or if the intervention was considered futile. The trial protocol permitted the inclusion of hemodynamically unstable patients. Ten randomized patients were excluded from data analysis due to a breach of inclusion criteria. Of the 316 who were randomized to EVAR, 275 (87%) had a confirmed diagnosis of ruptured AAA and 174 (64%) were considered anatomically suitable for EVAR. Endovascular aneurysm repair 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 to repair and was discharged. Of the 297 patients randomized to open repair, 261 (88%) 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=.62). After adjusting 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 OR, 0.94; 95% CI, 0.67 to 1.33; p=.73). Compared with men (adjusted OR, 0.44), women demonstrated a greater benefit from EVAR (adjusted OR, 1.18; p=.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<.001). IMPROVE investigators (2015) reported 1-year outcomes of the trial.[36] 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%) groups (OR, 0.85; 95% CI, 0.62 to 1.17; p=.325), with similar reintervention rates in both groups.[36] The EVAR group had shorter hospital stays (17 days) than the open repair group (26 days; p<.001). Quality of life, 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. The EuroQol outcome difference exceeded the minimally clinically important difference of 0.03.

Amsterdam Acute Aneurysm Trial

Reimerink et al (2013) reported on results from the AJAX trial, a regional multicenter randomized trial that compared EVAR with open repair in the treatment of ruptured AAA.[37] 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 CT angiography. Patients 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 CT angiography, 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 CT angiography, 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 endpoint (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, 5.4%; 95% CI, -13% to 23%). The 30-day mortality rate was 21% (12/57) in the EVAR group compared with 25% (15/59) in the open repair group (absolute risk reduction, 4.4%; 95% CI, -11% to 20%). The 2 groups had a similar median hospital stay and likelihood of intensive care unit admission. The investigators 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 groups. Also, 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 dans les Anéuvysmes aorto-iliaques Rompus

Desgranges et al (2015) reported on the 30-day and 1-year results of the multicenter ECAR pseudo-randomized trial.[38,] 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. The 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 characteristics were similar between the EVAR and open repair study groups. There were no significant differences between the EVAR and open repair group for the primary outcome of mortality at 30 days (18% vs. 24%, p=.239) or 1 year (30% vs. 35%, p=.296), although the trial was underpowered to detect a difference of this magnitude. The lower than expected mortality rate in the open repair group might have been due to the exclusion of patients with hemodynamic instability or unfavorable anatomic criteria. Despite a longer delay to repair with EVAR compared with open surgery (2.9 hours vs.1.3 hours, p=.005), EVAR reduced respiratory support time (59.3 hours vs. 180.3 hours, p=.007), pulmonary complications (15.4% vs. 41.5%, p=.05), total blood transfusion (6.8 units vs. 10.9 units, p=.020), and duration of intensive care unit stay (7 days vs. 11.9 days, p=.010).

Nonrandomized Comparative Studies

Edwards et al (2014) evaluated outcomes after EVAR and open repair for ruptured AAAs among traditional Medicare beneficiaries discharged from a U.S. hospital from 2001 to 2008.[39,] Overall, 10998 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 on 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<.001). The survival benefit persisted until 4 years post-surgery. 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<.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: Endovascular Aneurysm Repair as an Alternative to Open Repair for Ruptured Abdominal Aortic Aneurysm

For patients with ruptured AAAs to be candidates for endovascular repair, the lesions must be suitable for the endovascular devices, and patients must to be sufficiently stable to undergo CT evaluation. Three major RCTs and systematic reviews of these RCTs have published outcomes comparing EVAR with open surgery for patients with ruptured AAA. They reported that the 30-day and 1-year mortality rates for EVAR did not differ significantly from those for open surgery, while perioperative complications were reduced with EVAR. However, a large nonrandomized matched comparison demonstrated that EVAR is associated with a perioperative mortality benefit up to 4 years postsurgery, at the cost of the increased likelihood of the need for reintervention. Longer-term outcomes comparing EVAR with open surgery for ruptured aneurysms have not been reported.

Endovascular Aneurysm Repair for Smaller Aneurysms or for Patients Ineligible for Open Surgery

Clinical Context and Therapy Purpose

The purpose of endovascular stent grafts is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as nonsurgical therapy, in patients with AAA ineligible for open repair.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with AAA ineligible for open repair. 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.

Interventions

The therapy being considered is endovascular stent grafts.
Endovascular stent grafts can be used as minimally invasive alternatives to open surgical repair for treatment of 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.

Comparators

Comparators of interest include nonsurgical therapy.

Outcomes

The general outcomes of interest are OS, morbid events, treatment-related morbidity, and treatment-related mortality.

Available literature indicates long-term follow-up of 8 to 12 years.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Endovascular Aneurysm Repair for Smaller Aneurysms

Systematic Reviews

A Cochrane Review by Filardo et al (2015) summarized the evidence on interventions for small aneurysms (4.0 to 5.5 cm), either by open surgery or EVAR.[40] Four RCTs were identified, including 2 RCTs on EVAR (discussed below)[41,42] 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, 0.60 to 2.17). There was also no survival benefit for the trials of open surgery. An update of the 2015 Cochrane Review was attempted in 2020, but no new studies were identified for inclusion.[43]

Randomized Controlled Trials

Comparison of Surveillance Versus Aortic Endografting for Small Aneurysm Repair Trial

The Comparison of Surveillance Versus Aortic Endografting for Small Aneurysm Repair (CAESAR) trial compared the use of EVAR for small AAAs not meeting the current thresholds recommended for intervention with active surveillance.[41] 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 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/y, or symptomatic). If the 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 endpoint. Kaplan-Meier estimates of all-cause mortality were 10.1% for the surveillance group and 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.

De Rango (2011) published a follow-up on the CAESAR trial that reported on QOL outcomes.[44] Patients were assessed with the 36-Item Short-Form Health Survey at baseline, 6 months, 12 months, and yearly after that (mean follow-up, 31.8 months). Following EVAR, QOL scores in the EVAR arm improved while those in the observation arm worsened. At 6-month follow-up, QOL scores in the EVAR group were significantly higher than in the observation group, with significant differences found for 36-Item Short-Form Health Survey overall score (mean difference, 5.4; p=.002), physical domain score (mean difference, 3.8; p=.02), and mental domain score (mean difference, 6.0; p=.001). Over longer follow-up, scores in both the EVAR and observation groups declined, and scores did not differ significantly at 1 year and beyond.

Positive Impact of Endovascular Options for Treating Aneurysms Early Trial

The Positive Impact of Endovascular Options for Treating Aneurysms Early (PIVOTAL) trial randomized 728 patients with AAAs of 4 to 5 cm to early EVAR or ultrasound surveillance.[42] Patients were followed for a mean of 20 months for the primary outcomes (aneurysm rupture, aneurysm-related death, 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).

Endovascular Aneurysm Repair for Patients Ineligible for Open Repair

Randomized Controlled Trials

Greenhalgh et al (2005) reported on the EVAR2 trial, which compared endovascular repair for AAAs with no surgical intervention in patients unsuitable for open surgery.[6] Patients (338 of 404 eligible) who had been excluded from the EVAR1 trial were randomized to endovascular repair or medical management. Endovascular repair had a 9% 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. Also, 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.

Greenhalgh et al (2010) reported on a longer-term follow-up from the EVAR2 trial and evaluated 404 patients randomized to EVAR or no treatment.[45] The perioperative mortality rate 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 required reintervention for complications.

Sweeting et al (2017) reported on a very long-term follow-up of patients (mean follow-up, 12 years) for the EVAR2 trial and found that life expectancy was 4.2 years and was the same independent of treatment.[46] At 12 years, an estimated 5.3% (95% CI, 2.6% to 9.2%) of patients in the EVAR group were still living, compared with 8.5% (95% CI, 5.2% to 12.9%) of patients who received no intervention. There was no statistically significant difference between groups in total mortality (EVAR, 22.6 deaths per 100 person-years vs. no intervention, 22.1 deaths per 100 person-years; adjusted HR, 1.07; 95% CI, 0.86 to 1.34; p=.52). For aneurysm-related mortality, patients who received EVAR had a survival advantage at long-term follow-up (3.3 deaths per 100 person-years) compared with those who received no intervention (6.5 deaths per 100 person-years; adjusted HR, 0.55; 95% CI, 0.34 to 0.91). As previously discussed, substantial crossover and the small sample size at 8 years and beyond are limitations of this long-term follow-up. While there appears to be no OS advantage for the patients ineligible for open repair who receive EVAR compared with those who did not receive intervention for AAA, there is an apparent reduction in aneurysm-related mortality for EVAR patients.

Retrospective Studies

Khoury et al (2022) assessed outcomes after EVAR via the utilization of more contemporary post-EVAR2 data from the Vascular Quality Initiative database of the Society of Vascular Surgery (2003 to 2020). Patients were categorized as unfit (n=4435) or suitable (n=27036) for open AAA repair.[47] The primary outcome of the study was 30-day mortality. Secondary outcomes included length of stay, major adverse cardiovascular events (MACE), and 1-year mortality. Patients deemed unfit for open repair had significantly higher 30-day mortality (0.8% vs. 0.4%; p<.001), more perioperative MACE (5.1% vs. 2.2%; p<.001), and longer lengths of stay (p<.001) as compared to suitable patients. Unfit patients were also found to have worse 1-year survival as compared to suitable patients per Kaplan-Meier analysis (p<.001). However, unfit and suitable patients had significantly improved actual 1-year mortality with EVAR compared with predicted 1-year mortality without EVAR: 9.5% vs. 15.6% (p<.001) and 4.0% vs. 11.7% (p<.001), respectively. The mortality benefit after EVAR in patients deemed unfit was primarily restricted to those with smaller Gagne indices and larger aneurysm diameters. Those deemed unsuitable for open repair due to frailty or multiple reasons had worse 1-year cumulative survival compared with all other unfit patients. Limitations of this study included its retrospective design, lack of data regarding specifics of aneurysm anatomy, and lack of objective definition of what classifies a patient as "unfit".

Shahin et al (2023) performed a retrospective propensity score-matched analysis of patients with non-ruptured AAA who were deemed unfit for open surgical repair based on preoperative cardiopulmonary exercise testing, met use criteria for EVAR, and underwent EVAR or were managed conservatively.[48] The authors identified 350 patients, 244 of whom underwent 1:1 nearest-neighbor propensity score-matching based on age, sex, anaerobic threshold (a parameter obtained during cardiopulmonary exercise testing to determine fitness for AAA repair), and aneurysm size (n=122 matched patients for each of EVAR and conservative management). With mean follow-up of 9 years, median overall survival in the matched cohort was longer in patients who underwent EVAR than those who received conservative management (84 months vs. 30 months, respectively; p<.001). Cox proportional hazards regression indicated conservative management was independently associated with risk of all-cause death after adjusting for the effect of increasing age (HR, 4.46; 95% CI, 3.03 to 6.67). Among those who underwent EVAR, 17% underwent reintervention; the most frequent indication for reintervention was endoleak.

Section Summary: Endovascular Aneurysm Repair for Smaller Aneurysms or for Patients Ineligible for Open Repair

The evidence for EVAR is mixed in 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 reported that EVAR is associated with lower aneurysm-related mortality but not with 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. Contemporary retrospective analyses suggest a likely benefit to EVAR in patients deemed unfit for open AAA repair; one analysis indicated benefit may be reserved for those with lower Gagne Indices, larger AAA diameters, and lack of frailty, while a more recent propensity score-matched analysis indicated a mortality benefit in patients deemed unfit for open repair during preoperative cardiopulmonary exercise testing who met use criteria for EVAR.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology and American Heart Association

In 2022, the American College of Cardiology and the American Heart Association (ACC/AHA) published a guideline for the management of aortic disease, including abdominal aortic aneurysm (AAA).[49,] Recommendations from the guideline regarding AAA repair are listed in Table 7.

Table 7. Guideline on Management of Patients with Aortic Disease: Abdominal Aortic Aneurysm Repair

Recommendation	COR	LOE
In patients with nonruptured AAA with low to moderate operative risk and suitable anatomy, a shared decision-making process weighing the risks and benefits of endovascular versus open repair is recommended.	I	A
In patients with nonruptured AAA with high operative risk, endovascular repair is reasonable to reduce risk of 30-day morbidity, mortality, or both.	IIa	B-NR
In patients with nonruptured AAA with moderate to high operative risk and suitable anatomy for an FDA-approved fenestrated endovascular device, endovascular repair is reasonable over open repair to reduce risk of perioperative complications.	IIa	B-NR
In patients with ruptured AAA with suitable anatomy, endovascular repair is recommended over open repair to reduce risk of morbidity and morality.	I	B-R

AAA: abdominal aortic aneurysm; COR: class of recommendation; FDA: Food and Drug Administration; LOE: level of evidence; NR: nonrandomized; R: randomized.

In 2011, the ACC/AHA released an update to their 2005 guidelines on the management of AAAs that focused on the management of patients with peripheral artery disease.[50,] These guidelines made the following recommendations (Table 8).

Table 8. Guidelines on Management of Patients With Peripheral Artery Disease

Recommendation	COR	LOE
Open or endovascular repair of infrarenal AAAs and/or common iliac aneurysms is indicated inpatients who are good surgical candidates	I	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	I	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	IIa	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	IIb	C

AAA: abdominal aortic aneurysm; COR: class of recommendation; LOE: level of evidence.

In 2006, the ACC/AHA suggested in their professional guidelines, based on both randomized and nonrandomized trials, that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open surgeries.[51]

Society of Interventional Radiology

In 2010, the Society of Interventional Radiology developed guidelines on the use of endovascular aneurysm repair (EVAR) that were endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association.[52] These guidelines indicated 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 (i) the detection and, if possible, the characterization of endoleaks; (ii) 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; (iii) detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture; and (iv) evaluation of the long-term performance of the endoprosthesis."

Society for Vascular Surgery

In 2018, the Society for Vascular Surgery published guidelines for the treatment of AAAs.[53] As in previous publications, these guidelines indicated that open surgery and EVAR are options for patients with aneurysms that meet the current treatment threshold. These guidelines also made the following recommendations (Table 9).

Table 9. Guidelines on Management of Patients With Aneurysms

Recommendation	QOE	LOR
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	Moderate	Strong
EVAR may be considered for high-risk patients unfit for surgical repair	Low	Weak
For patients with ruptured aneurysm, immediate repair is recommended	High	Strong

AAA: abdominal aortic aneurysm; EVAR: endovascular aneurysm repair; LOR: level of recommendation; QOE: quality of evidence.

U.S. Preventive Services Task Force Recommendations

Recommendations from the U.S. Preventive Services Task Force (USPSTF) on AAA screening were updated on December 10, 2019.[54] The USPSTF notes the following in their section on "Current Practice" as it relates to this topic:

"The standard of care for elective repair is that patients with an AAA of 5.5 cm or larger in diameter should be referred for surgical intervention with either open repair or EVAR. This recommendation is based on RCTs conducted in men. The AAA size needed for surgical intervention in women may differ. As a result, guidelines from the Society for Vascular Surgery recommend repairing AAAs between 5.0 and 5.4 cm in diameter in women. However, concerns about poorer surgical outcomes in women, who have more complex anatomy and smaller blood vessels, have led some to caution against lowering the threshold for surgical intervention in women."

National Institute for Health and Care Excellence

Recommendations for the diagnosis and management of AAAs were published by the National Institute for Health and Care Excellence (NICE) in March 2020.[55,] Recommendations for repairing unruptured aneurysms include:

- "1.5.1: Consider aneurysm repair for people with an unruptured abdominal aortic aneurysm (AAA), if it is:
    - symptomatic
    - asymptomatic, larger than 4.0 cm, and has grown by more than 1 cm in 1 year (measured inner-to-inner maximum anterior-posterior aortic diameter on ultrasound)
    - asymptomatic and 5.5 cm or larger (measured inner-to-inner maximum anterior-posterior aortic diameter on ultrasound)."
- "1.5.4: Consider endovascular aneurysm repair (EVAR) for people with unruptured AAAs who meet the criteria in recommendation 1.5.1 and who have abdominal copathology, such as a hostile abdomen, horseshoe kidney or a stoma, or other considerations, specific to and discussed with the person, that may make EVAR the preferred option"
- "1.5.5: Consider EVAR or conservative management for people with unruptured AAAs meeting the criteria in recommendation 1.5.1 who have anaesthetic risks and/or medical comorbidities that would contraindicate open surgical repair."

Recommendations for repairing ruptured aneurysms include:

- "1.6.1: Consider endovascular aneurysm repair (EVAR) or open surgical repair for people with a ruptured infrarenal abdominal aortic aneurysm (AAA). Be aware that:
    - EVAR provides more benefit than open surgical repair for most people, especially men over 70 and women of any age
    - Open surgical repair is likely to provide a better balance of benefits and harms in men under 70."
- "1.6.2: Consider open surgical repair for people with a ruptured AAA if standard EVAR is unsuitable."

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01937949[a]	Clinical Outcomes and Quality of Life Measures in Patients Treated for Complex Abdominal Aortic Aneurysms With Fenestrated Stent Grafts	200	May 2030
NCT01726257[a]	Prospective, Multicenter, Single Arm Safety and Effectiveness Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix® System: A Pivotal and Continued Access Study	333	Dec 2022
NCT03966521	The British Society of Endovascular Therapy ConformabLe EndoVascular Repair (BSET-CLEVAR) Registry	150	Dec 2022
NCT02996396[a]	Multicenter, Observational, Registry to Assess Outcomes of Patients Treated With the CE Nellix® System for Endovascular Abdominal Aortic Aneurysm Repair	300	Nov 2024
NCT03298477[a]	Prospective, Multicenter, Single Arm Safety and Effectiveness Confirmatory Study of Endovascular Abdominal Aortic Aneurysm	98	Aug 2025

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Repair Using the Nellix System IDE Study (EVAS 2 Confirmatory IDE Study)		
NCT02489539[a]	Assessment of the GORE® EXCLUDER® Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms	190	Dec 2027
NCT03180996[a]	A Prospective, Global, Multicentre, Real World Outcome Study of Fenestrated Endovascular Aneurysm Repair Using the Fenestrated Anaconda™ Device	160	Dec 2030
NCT03446287	Clinical Outcomes and Quality of Life Measures in Patients Treated With Open Surgical Repair for Complex Aortic Aneurysms	150	Dec 2026
Unpublished			
NCT02485496[a]	SECURE - A poSt-market Registry in Patients With infraEnal aortiC Aneurysm Undergoing endovasculaR Stenting With the New E-tegra Stent Graft System	100	Dec 2021
NCT04220177[a]	Prospective, Open-label, Multicenter, Non-randomized Clinical Study to Determine the Safety and Efficacy of SETA LATECBA Stent Graft for Endovascular Repair Therapy (EVAR) in Subjects With Abdominal Aortic Aneurysm (AAA)	42	Mar 2022

NCT: national clinical trial.

[a] Denotes an industry-sponsored or cosponsored trial.

References

1. Atkins AD, Atkins MD. Branched and Fenestrated Aortic Endovascular Grafts. Methodist Debakey Cardiovasc J. 2023; 19(2): 15-23. PMID 36910555
2. Blum U, Voshage G, Lammer J, et al. Endoluminal stent-grafts for infrarenal abdominal aortic aneurysms. N Engl J Med. Jan 02 1997; 336(1): 13-20. PMID 8970935
3. Ernst CB. Current therapy for infrarenal aortic aneurysms. N Engl J Med. Jan 02 1997; 336(1): 59-60. PMID 8970942
4. White RA, Donayre CE, Walot I, et al. Modular bifurcation endoprosthesis for treatment of abdominal aortic aneurysms. Ann Surg. Sep 1997; 226(3): 381-9; discussion 389-91. PMID 9339944
5. 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 306-8. PMID 9950987
6. EVAR trial participants. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomised controlled trial. Lancet. Jun 2005; 365(9478): 2187-92. PMID 15978926
7. EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. Lancet. Jun 2005; 365(9478): 2179-86. 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 09 2005; 352(23): 2398-405. PMID 15944424
9. 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 2004; 364(9437): 843-8. PMID 15351191
10. 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): 1607-18. PMID 15483279
11. 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): 10-9. PMID 14718804

12. 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): 382-9. PMID 15838467
13. 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): 491-6. PMID 14981436
14. Paravastu SC, Jayarajasingam R, Cottam R, et al. Endovascular repair of abdominal aortic aneurysm. Cochrane Database Syst Rev. Jan 23 2014; (1): CD004178. PMID 24453068
15. 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
16. AlOthman O, Bobat S. Comparison of the Short and Long-Term Outcomes of Endovascular Repair and Open Surgical Repair in the Treatment of Unruptured Abdominal Aortic Aneurysms: Meta-Analysis and Systematic Review. Cureus. Aug 12 2020; 12(8): e9683. PMID 32923276
17. Antoniou GA, Juszczak MT, Antoniou SA, et al. Editor's Choice - Fenestrated or Branched Endovascular versus Open Repair for Complex Aortic Aneurysms: Meta-Analysis of Time to Event Propensity Score Matched Data. Eur J Vasc Endovasc Surg. Feb 2021; 61(2): 228-237. PMID 33288434
18. Bulder RMA, Bastiaannet E, Hamming JF, et al. Meta-analysis of long-term survival after elective endovascular or open repair of abdominal aortic aneurysm. Br J Surg. Apr 2019; 106(5): 523-533. PMID 30883709
19. Chen ZG, Tan SP, Diao YP, et al. The long-term outcomes of open and endovascular repair for abdominal aortic aneurysm: A meta-analysis. Asian J Surg. Oct 2019; 42(10): 899-906. PMID 30914154
20. Li B, Khan S, Salata K, et al. A systematic review and meta-analysis of the long-term outcomes of endovascular versus open repair of abdominal aortic aneurysm. J Vasc Surg. Sep 2019; 70(3): 954-969.e30. PMID 31147117
21. Yokoyama Y, Kuno T, Takagi H. Meta-analysis of phase-specific survival after elective endovascular versus surgical repair of abdominal aortic aneurysm from randomized controlled trials and propensity score-matched studies. J Vasc Surg. Oct 2020; 72(4): 1464-1472.e6. PMID 32330598
22. 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): 571-6. PMID 21820922
23. Ulug P, Sweeting MJ, von Allmen RS, et al. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis. Lancet. Jun 24 2017; 389(10088): 2482-2491. PMID 28455148
24. 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): 1988-97. PMID 23171095
25. Lederle FA, Kyriakides TC, Stroupe KT, et al. Open versus Endovascular Repair of Abdominal Aortic Aneurysm. N Engl J Med. May 30 2019; 380(22): 2126-2135. PMID 31141634
26. 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): 1881-9. PMID 20484396
27. 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): 1863-71. PMID 20382983
28. 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): 935-42. PMID 21484775
29. 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.e1. PMID 21276681

30. 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): 442-8. PMID 24220121
31. 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): 380-7. PMID 24485844
32. 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): 1229-39. PMID 26104471
33. Badger S, Forster R, Blair PH, et al. Endovascular treatment for ruptured abdominal aortic aneurysm. Cochrane Database Syst Rev. May 26 2017; 5(5): CD005261. PMID 28548204
34. Antonopoulos CN, Moulakakis KG, Rorris FP, et al. Individual Patient Data Meta-Analysis of 10-Year Follow-Up after Endovascular and Open Repair for Ruptured Abdominal AorticAneurysms. Ann Vasc Surg. Jan 21 2023. PMID 36690248
35. Powell JT, Sweeting MJ, Thompson MM, et al. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial. BMJ. Jan 13 2014; 348: f7661. PMID 24418950
36. Braithwaite B, Cheshire NJ, Greenhalgh RM, et al. 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
37. 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): 248-56. PMID 23549424
38. Desgranges P, Kobeiter H, Katsahian S, et al. Editor's Choice - ECAR (Endovasculaire ou Chirurgie dans les Anévrysmes 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): 303-10. PMID 26001320
39. 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): 575-82. PMID 24342064
40. Filardo G, Powell JT, Martinez MA, et al. Surgery for small asymptomatic abdominal aortic aneurysms. Cochrane Database Syst Rev. Feb 08 2015; 2015(2): CD001835. PMID 25927098
41. 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
42. 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): 1081-7. PMID 20304589
43. Ulug P, Powell JT, Martinez MA, et al. Surgery for small asymptomatic abdominal aortic aneurysms. Cochrane Database Syst Rev. Jul 01 2020; 7(7): CD001835. PMID 32609382
44. 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): 324-31. PMID 21145269
45. 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): 1872-80. PMID 20382982
46. Sweeting MJ, Patel R, Powell JT, et al. Endovascular Repair of Abdominal Aortic Aneurysm in Patients Physically Ineligible for Open Repair: Very Long-term Follow-up in the EVAR-2 Randomized Controlled Trial. Ann Surg. Nov 2017; 266(5): 713-719. PMID 28742684
47. Khoury MK, Heid CA, Rectenwald JE, et al. Understanding who benefits from endovascular aortic repair in those deemed unfit for open repair. J Vasc Surg. Aug 2022; 76(2): 419-427.e3. PMID 35227800
48. Shahin Y, Dixon S, Kerr K, et al. Endovascular aneurysm repair offers a survival advantage and is cost-effective compared with conservative management in patients physiologically unfit for open repair. J Vasc Surg. Feb 2023; 77(2): 386-395.e3. PMID 36152982

49. Isselbacher EM, Preventza O, Hamilton Black Iii J, et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. Dec 13 2022; 80(24): e223-e393. PMID 36334952
50. 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 01 2011; 58(19): 2020-45. PMID 21963765
51. 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): 1239-312. PMID 16545667
52. 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): 1632-55. PMID 20884242
53. Chaikof EL, Dalman RL, Eskandari MK, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. J Vasc Surg. Jan 2018; 67(1): 2-77.e2. PMID 29268916
54. Owens DK, Davidson KW, Krist AH, et al. Screening for Abdominal Aortic Aneurysm: US Preventive Services Task Force Recommendation Statement. JAMA. Dec 10 2019; 322(22): 2211-2218. PMID 31821437
55. National Institute for Health and Care Excellence (NICE). Abdominal aortic aneurysm: diagnosis and management. NICE guideline [NG156]. March 19, 2020. Accessed March 31, 2023. https://www.nice.org.uk/guidance/ng156

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
- Imaging report(s) of abdominal aortic aneurysm(s), including measurements
- Name of endovascular stent graft used
- Reason for endovascular stent graft (e.g., disorder of abdominal aorta)
- Procedure report(s)

Post Service (in addition to the above, please include the following):

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0254T	Endovascular repair of iliac artery bifurcation (e.g., aneurysm, pseudoaneurysm, arteriovenous malformation, trauma, dissection) using bifurcated endograft from the common iliac artery into both the external and internal iliac artery, including all selective and/or nonselective catheterization(s) required for device placement and all associated radiological supervision and interpretation, unilateral
	34701	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 (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
	34702	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 rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
	34703	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
	34704	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
	34705	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level

Type	Code	Description
		of the renal arteries to the iliac bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)
	34706	Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-bi-iliac 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 iliac bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the iliac bifurcation; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer, traumatic disruption)
	34707	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 (e.g., 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 rupture including temporary aortic and/or iliac balloon occlusion, when performed (e.g., 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)

Type	Code	Description
	34812	Open femoral artery exposure for delivery of endovascular prosthesis, by groin incision, unilateral (List separately in addition to code for primary procedure)
	34820	Open iliac artery exposure for delivery of endovascular prosthesis or iliac occlusion during endovascular therapy, by abdominal or retroperitoneal incision, unilateral (List separately in addition to code for primary procedure)
	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
	34839	Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time
	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	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
	34843	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
	34844	Endovascular repair of visceral aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
	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)

Type	Code	Description
	34846	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 two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
	34847	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 three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
	34848	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 four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
	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
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/31/2015	BCBSA Medical Policy adoption
07/01/2016	Policy title change from "Endovascular Grafts for Abdominal Aortic Aneurysms"
07/01/2017	Policy revision without position change
01/01/2018	Coding update
07/01/2018	Policy revision without position change
08/01/2019	Policy revision without position change
08/01/2023	Policy reactivated. Previously archived from 07/01/2020 to 07/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	**Endovascular Stent Grafts for Abdominal Aortic Aneurysms 7.01.67** **Policy Statement:** I. The use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) as a treatment of abdominal aortic aneurysms (AAAs) may be considered **medically necessary** in **any** of the following clinical situations: A. A ruptured abdominal aortic aneurysm (see policy guidelines section) B. An aneurysmal diameter greater than 5.0 centimeters (cm) C. An aneurysmal diameter of 4 to 5.0 cm that has increased in size by 0.5 cm in the last 6 months D. An aneurysmal diameter that measures twice the size of the normal infrarenal aorta II. The use of endoprostheses approved by the FDA as a treatment of AAAs is considered **investigational** when the above criteria are not met, including but not limited to, **either** of the following clinical situations: A. 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 B. Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery