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MEDICAL POLICY – 7.01.601

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

BCBSA Ref. Policy:	7.01.67	
Effective Date:	**Mar. 4, 2026**	RELATED MEDICAL POLICIES:
Last Revised:	Nov. 11, 2025	N/A
Replaces:	N/A	

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Introduction

Abdominal aortic aneurysms (AAAs) are a buldge or weak spot in the wall of the main blood vessel that carries blood from the heart to the lower body. If the aneyrysm grows too large, it can burst and cause life-threatening bleeding. Instead of open surgery, doctors can use a minimally invasive procedure called endovascular aneurysm repair (EVAR). During EVAR, a thin tube called a catheter is inserted through a small cut in the groin and guided into the aorta. A stent graft, a fabric tube supported by a metal mesh, is placed inside the weakened area to strengthen the artery and allow blood to flow safely through it. This approach usually means smaller incisions, shorter recovery times, and less risk of complications compared to traditional open surgery. This policy discusses when this technique is considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Medical Necessity
Endoprostheses	**The use of endoprostheses approved by the US 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:** • An aneurysmal diameter greater than 5.0 cm • An aneurysmal diameter of 4 to 5.0 cm that has increased in size by 0.5 cm in the last 6 months • An aneurysmal diameter that measures twice the size of the normal infrarenal aorta • A ruptured AAA (see **Related Information**) (this is an emergent condition, prior authorization not required)

Procedure	Not Medically Necessary
Endoprostheses	**The use of endoprostheses approved by the FDA as a treatment of AAAs is considered not medically necessary when the above criteria are not met, including but not limited to the following clinical situations:** • Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery • Treatment of aneurysms that do meet the recommended threshold for surgery in individuals who are ineligible for open repair due to physical limitations or other factors (e.g. prohibitive surgical risk, frailty)

Documentation Requirements
The patient's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the relevant history and physical and the aneurysmal diameter

Coding

Code	Description
CPT	

Code	Description
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 (eg, 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 (eg, 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 (eg, 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 (eg, 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 (eg, 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

Code	Description
	and/or iliac balloon occlusion, when performed (eg, 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 (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation)
34708	Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting, when performed, unilateral; for rupture including temporary aortic and/or iliac balloon occlusion, when performed (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, traumatic disruption)
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)
34717	Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral (List separately in addition to code for primary procedure)
34718	Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone

Code	Description
	angioplasty/stenting, when performed, for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral
34841	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34842	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844	Endovascular repair of visceral aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])

Code	Description
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (eg, aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
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

Related Information

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

- The individual must be sufficiently stable to undergo detailed computed tomography examination for anatomic measurements,
- The aneurysm should be anatomically appropriate for endovascular repair, and
- Specialized personnel should be available.
- To monitor for leaking of the graft after implantation, individuals will typically undergo routine imaging with computed tomography or ultrasonography every 6 to 12 months, or more frequently if perivascular leaks or aneurysm enlargement are detected.

Benefit Application

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

Evidence Review

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.

Background

Management of a clinically significant abdominal aortic aneurysm (AAA) consists of surgical excision with the placement of a sutured woven graft or endovascular grafting.[1] 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 were 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.[2,3,4,5]

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.

Summary of Evidence

For individuals who have abdominal aortic aneurysms (AAAs) eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs and cohort studies. Relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of 4 RCTs comparing EVAR with open repair for elective treatment of AAAs has indicated that neither approach is clearly superior to the other. While endovascular aneurysm repair (EVAR) is associated with an early reduction in mortality, outcomes at 5 years or longer have generally shown greater reintervention rates and endovascular mortality and comparable OS rates for EVAR and open repair. Thus, the early advantage of EVAR is offset by a higher rate of late complications over the long-term. Based on these data, EVAR may be considered as an alternative to open surgery in patients who are candidates for both procedures. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have ruptured AAAs who receive endovascular stent grafts, the evidence includes RCTs, systematic reviews of RCTs, and nonrandomized comparative studies. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. For patients with ruptured AAAs, evidence from 3 major RCTs and 2 meta-analyses has indicated that short- and intermediate-term survival (up to 1 year) following EVAR is comparable with open repair, while perioperative complications are reduced with EVAR. Evidence from a large nonrandomized matched comparison demonstrated that EVAR is associated with a perioperative mortality benefit up to 4 years post surgery, at the cost of the increased likelihood of the need for reintervention. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have AAAs ineligible for open repair who receive endovascular stent grafts, the evidence includes RCTs and retrospective analyses. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. At least 2 RCTs have compared EVAR with no surgical intervention for patients ineligible for open repair, either because of aneurysm size or prohibitive surgical risk. These trials did not report superior outcomes with EVAR and thus do not support the use of EVAR in this population. One retrospective database analysis suggests a likely benefit to EVAR in patients deemed unfit for open AAA repair, which may be

reserved for those with lower Gagne Indices, larger AAA diameters, and lack of frailty, while a propensity score-matched analysis indicates a long-term survival benefit with EVAR relative to conservative management in patients with AAA deemed unfit for open repair based on cardiopulmonary exercise testing. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

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

Table 1. 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
NCT03298477[a]	Prospective, Multicenter, Single Arm Safety and Effectiveness Confirmatory Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix System IDE Study (EVAS 2 Confirmatory IDE Study)	98	Aug 2025
NCT02489539[a]	Assessment of the GORE EXCLUDER Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms	175	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
Unknown			
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

NCT No.	Trial Name	Planned Enrollment	Completion Date
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
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	105	Dec 2022

NCT: national clinical trial. [a] Denotes an industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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).[52] Recommendations from the guideline regarding AAA repair are listed in **Table 2**.

Table 2. 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.[53] These guidelines made the following recommendations (**Table 3**).

Table 3. 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 in patients 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

Recommendation	COR	LOE
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.[54]

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.[55] 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.[56] 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 4**).

Table 4. 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.

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.[58] 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."

US Preventive Services Task Force Recommendations

Recommendations from the US Preventive Services Task Force (USPSTF) on AAA screening were updated on December 10, 2019.[57] 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."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A large number of endovascular grafts have been approved by the US Food and Drug Administration (FDA) through the premarket approval (PMA) process for the treatment of AAAs (**Table 5**). The original PMA dates are shown. Most stents have undergone device modification, name changes, and have approved supplements to the original PMA.

FDA product code MIH.

Table 5. 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
Ovation Abdominal Stent Graft System	Endologix	2012	P120006
Aorfix AAA Flexible Stent Graft System	Lombard Medical	2013	P110032
Incraft AAA Stent Graft System	Cordis	2018	P150002
TREO Abdominal Stent-Graft System	Bolton Medical	2020	P190015
Alto Abdominal Stent Graft System	Endologix, LLC	2023	P120006

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

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History

Date	Comments
12/01/25	New policy, approved November 11, 2025, effective for dates of service on or after March 4, 2026, following 90-day provider notification. Add to Surgery section. Policy created with literature review through March 17, 2025; references added. The use of endoprostheses approved by the FDA as a treatment of abdominal aortic aneurysms (AAAs) may be considered medically necessary when criteria are met.