BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy #: 645
Latest Review Date: May 2022
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **endovascular stent grafts approved by the FDA and used according to device indications,** as a **covered benefit** for the treatment of abdominal aortic aneurysms.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

Conventional management of a clinically significant abdominal aortic aneurysm (AAA) consists of surgical excision with placement of a sutured woven graft. Surgical excision is associated with a perioperative mortality rate between 1% and 5%. Perioperative morbidity and mortality are highest in older female patients with cardiac, pulmonary, or kidney disease; the most common cause of death is multisystem organ failure.

Due to the high mortality rate, endovascular prostheses have been developed as a 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.

Several types of grafts are currently in use: straight grafts, in which both ends are anchored to the infrarenal aorta, and bifurcated grafts, in which the proximal end is anchored to the infrarenal

aorta, and the distal ends are anchored to the iliac arteries. Fenestrated grafts have also been investigated. These grafts are designed with openings in the wall that can be placed across the renal or celiac arteries while still protecting vessel patency through these critical arteries. In addition, extensions can be placed from inside the main endograft body into the visceral arteries to create a hemostatic seal.

KEY POINTS:

The most recent literature update covers the period through March 28, 2022.

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), systematic reviews of RCTs, and cohort studies. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of 4 RCTs comparing endovascular aneurysm repair (EVAR) with open repair for elective treatment of AAAs has indicated that neither approach is clearly superior to the other. While EVAR is associated with an early reduction in mortality, outcomes at 5 years or longer have shown a greater reintervention rates and endovascular mortality and comparable overall survival 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 a meaningful 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 overall survival, morbid events, and treatment-related mortality and morbidity. For patients with ruptured AAAs, evidence from 3 RCTs and 2 meta-analyses have 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 a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Cardiology Foundation and American Heart Association

Updated guidelines on the management of AAAs were released by the American College of Cardiology Foundation and the American Heart Association in 2011 as a focused update to the 2005 guidelines on the management of patients with peripheral artery disease. These guidelines made the following recommendations (see Table 1).

Table 1: 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
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.

Guidelines from the American College of Cardiology and American Heart Association (2006), based on both randomized and nonrandomized trials, have suggested that endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complication from open surgeries.

Society of Interventional Radiology et al
Guidelines on the use of EVAR were developed jointly by the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, and the Canadian Interventional Radiology Association in 2010. 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

1. the detection and, if possible, the characterization of endoleaks;
2. 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;
3. detection of mechanical changes in the stent-graft, such as migration, kinking, or fracture;
4. evaluation of the long-term performance of the endoprosthesis."

Society for Vascular Surgery

The Society for Vascular Surgery published guidelines for the treatment of AAAs in 2018. 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 contained the following statements and recommendations (see Table 2).

Table 2: 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. 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."

KEY WORDS:

EVAR, AAA, abdominal aortic aneurysm, endovascular repair, AneuRx® Prosthesis System, Gore® Excluder®, Zenith® AAA Endovascular Graft, Endologix Powerlink®, Talent® Abdominal Stent Graft System, Endurant® II, Ovation™, Aorfix™, abdominal aneurysm

APPROVED BY GOVERNING BODIES:

A large number of endovascular grafts have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process for treatment of abdominal aortic aneurysms (see Table 3). The original PMA dates are shown. Most stents have undergone device modification, name changes, and have approved supplements to the original PMA.

Table 3: Abdominal Aortic Stent Grafts Approved by FDA

Stent Name	PMA Applicant	Approval Date	PMA No.
AneuRx® Prosthesis System (AneuRx AAAdvantage Stent Graft)	Medtronic Vascular	1999	P990020
Ancure® Aortoiliac System	Guidant Endovascular Technologies	2002	P990017
Gore® Excluder®	W.L. Gore & Associates	2002	P020004
Zenith® AAA Endovascular Graft	Cook	2003	P020018
Talent® Abdominal Stent Graft System	Medtronic	2008	P070027
Endologix Powerlink® (Afx Endovascular AAA system)	Endologix	2004	P040002
Endurant® II AAA Stent Graft System	Medtronic	2010	P100021
Relay Thoracic Stent Graft with Plus Delivery System	Bolton Medical	2012	P110038
Valiant Thoracic Stent Graft System	Medtronic	2011	P100040
Ovation™ Abdominal Stent Graft System	TriVascular	2012	P120006

Aorfix™ AAA Flexible Stent Graft System	Lombard Medical	2013	P110032
Incraft® AAA Stent Graft System	Cordis	2018	P150002

PMA: premarket approval.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

The overall procedure involves 4 steps: establishing vascular access, introducing catheters and guide wires into the arterial system, deploying the endoprosthesis, and radiologic supervision.

Below are the codes for the procedure.

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 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)
34709	Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac

	aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed, per vessel treated (List separately in addition to code for primary procedure)
34710	Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed; initial vessel treated
34711	Delayed placement of distal or proximal extension prosthesis for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, endoleak, or endograft migration, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed; each additional vessel treated (List separately in addition to code for primary procedure)
34712	Transcatheter delivery of enhanced fixation device(s) to the endograft (eg, anchor, screw, tack) and all associated radiological supervision and interpretation
34713	Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral (List separately in addition to code for primary procedure)
34714	Open femoral artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by groin incision, unilateral (List separately in addition to code for primary procedure)
34715	Open axillary/subclavian artery exposure for delivery of endovascular prosthesis by infraclavicular or supraclavicular incision, unilateral (List separately in addition to code for primary procedure)
34716	Open axillary/subclavian artery exposure with creation of conduit for delivery of endovascular prosthesis or for establishment of cardiopulmonary bypass, by infraclavicular or supraclavicular incision, unilateral (List separately in addition to code for primary procedure)
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)
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 endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34842	;including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34843	;including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34844	;including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (e.g., aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery)
34846	;including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34847	;including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
34848	;including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s])
36200	Induction of catheter, aorta

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Adopted for Blue Advantage, June 2017
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Medical Policy Group, December 2017
Medical Policy Group, June 2018
Medical Policy Group, June 2019
Medical Policy Group, June 2020
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