



# Louisiana

## Endovascular Stent Grafts for Abdominal Aortic Aneurysms

**Policy #** 00035

**Original Effective Date:** 01/27/2003

**Current Effective Date:** 07/13/2020

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

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

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

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

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

#### Patient Selection Criteria

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

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

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### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

The use of endoprostheses approved by the U.S. FDA as a treatment of AAAs are considered to be **investigational\***, including but not limited to the following clinical situations:

- Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery;
- Treatment of aneurysms that do meet the recommended threshold for surgery in patients who are ineligible for open repair due to physical limitations or other factors.

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

### **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 examination for anatomic measurements,
- The aneurysm should be anatomically appropriate for endovascular repair, and
- Specialized personnel should be available.

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

### **Background/Overview**

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.

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

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

A large number of endovascular grafts have been approved by the U.S. 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.

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**Table 1. Abdominal Aortic Stent Grafts Approved by FDA**

Stent Name	PMA Applicant	Approved	PMA No.
AneuRx <sup>®‡</sup> Prosthesis System (AneuRx AAA Advantage Stent Graft)	Medtronic Vascular	1999	P990020
Ancure <sup>®‡</sup> Aortoiliac System	Guidant Endovascular Technologies	2002	P990017
Gore <sup>®‡</sup> Excluder <sup>®‡</sup>	W.L. Gore & Associates	2002	P020004
Zenith <sup>®‡</sup> AAA Endovascular Graft	Cook	2003	P020018
Endologix Powerlink <sup>®‡</sup> (Afx Endovascular AAA system)	Endologix	2004	P040002
Talent <sup>®‡</sup> Abdominal Stent Graft System	Medtronic	2008	P070027
Endurant <sup>®‡</sup> 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 <sup>™‡</sup> Abdominal Stent Graft System	TriVascular	2012	P120006
Aorfix <sup>™‡</sup> AAA Flexible Stent Graft System	Lombard Medical	2013	P110032

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

### Rationale/Source

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.

For individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and nonrandomized comparative studies. The relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. Evidence from a patient-level meta-analysis of four 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 five years or longer have shown

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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 a meaningful improvement in the net health outcome.

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

For individuals who have AAAs ineligible for open repair who receive endovascular stent grafts, the evidence includes RCTs. The relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. At least two 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. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

#### **American College of Cardiology Foundation and American Heart Association**

Updated guidelines on the management of abdominal aortic aneurysms (AAAs) were released by the American College of Cardiology Foundation and the American Heart Association (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 2).

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**Table 2. Guidelines on Management of Patients With Peripheral Artery Disease**

<b>Recommendation</b>	<b>COR</b>	<b>LOE</b>
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.

Professional 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**

Guidelines on the use of endovascular aneurysm repair (EVAR) were developed by the Society of Interventional Radiology (2010) and endorsed by the Cardiovascular and Interventional Radiological Society of Europe and the Canadian Interventional Radiology Association. 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%.”

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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

The Society for Vascular Surgery (2018) published guidelines for the treatment of AAAs. 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 (see Table 3).

**Table 3. 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

Not applicable.

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**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 unpublished trials that might influence this review are listed in Table 4.

**Table 4. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01878240	Prevention of Type II Endoleaks During Endovascular Treatment of Abdominal Aortic Aneurysm: Endovascular Treatment Versus Combination With Coil Embolisation of the Aneurysmal Sac	100	May 2019
NCT00583050	Endovascular Exclusion of Thoracoabdominal Aortic Aneurysms or Abdominal Aneurysms Utilizing Fenestrated/Branched Stent-Grafts	1440	Dec 2020
NCT01937949 <sup>a</sup>	Clinical Outcomes and Quality of Life Measures in Patients Treated for Complex Abdominal Aortic Aneurysms With Fenestrated Stent Grafts	200	Dec 2020
NCT03446287	Clinical Outcomes and Quality of Life Measures in Patients Treated With Open Surgical Repair for Complex Aortic Aneurysms	150	Dec 2020
NCT01726257 <sup>a</sup>	Prospective, Multicenter, Single Arm Safety and Effectiveness Study of Endovascular Abdominal Aortic Aneurysm Repair Using the Nellix <sup>®</sup> System: A Pivotal and Continued Access Study	429	Jun 2021
NCT02485496 <sup>a</sup>	SECURE - A post-market Registry in Patients With infraEnal aortic Aneurysm Undergoing	100	Oct 2021

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	endovascular Stenting With the New E-tegra Stent Graft System		
NCT02996396 <sup>a</sup>	Multicenter, Observational, Registry to Assess Outcomes of Patients Treated With the CE Nellix <sup>TM†</sup> System for Endovascular Abdominal Aortic Aneurysm Repair	300	Oct 2023
NCT03298477 <sup>a</sup>	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)	90	May 2024
NCT02489539 <sup>a</sup>	Assessment of the GORE <sup>®†</sup> EXCLUDER <sup>®†</sup> Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms	190	Dec 2024
NCT03180996 <sup>a</sup>	A Prospective, Global, Multicentre, Real World Outcome Study of Fenestrated Endovascular Aneurysm Repair Using the Fenestrated Anaconda <sup>TM†</sup> Device	160	Sep 2029

NCT: national clinical trial.

<sup>a</sup> Denotes an industry-sponsored or cosponsored trial.

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# Louisiana

## Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035

Original Effective Date: 01/27/2003

Current Effective Date: 07/13/2020

### **Policy History**

Original Effective Date: 01/27/2003

Current Effective Date: 07/13/2020

11/21/2002	Medical Policy Committee review
01/27/2003	Managed Care Advisory Council approval
01/20/2004	Medical Policy Committee review. Format revision. Coverage eligibility unchanged.
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged
01/31/2005	Managed Care Advisory Council approval
05/17/2005	Medical Policy Committee review. Format revision. Policy statement changed from endoprostheses (i.e., endovascular grafts) as a treatment of abdominal aortic aneurysms (infrarenal abdominal or aortoiliac aneurysms) to: the use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms. Patient selection criteria expanded to include; "The use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms may be considered medically necessary as a treatment of abdominal aortic aneurysms in any of the following clinical situations, consistent with the FDA-labeled indications for the AneurRx device." Investigational statement added to address non FDA-Approved devices and situations when patient selection criteria are not met.
05/23/2005	Managed Care Advisory Council approval
07/07/2006	Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/02/2006	Medical Director Review
08/09/2006	Medical Policy Committee approval. Rationale /Source and rationale updated.
06/13/2007	Medical Director review
06/20/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Policy statement added for treatment of ruptured abdominal aortic aneurysm as investigational.
08/06/2009	Medical Policy Committee approval

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08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Changed coverage statement from investigational to eligible for coverage with criteria for ruptured abdominal aortic aneurysms.
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. For clarification, added that the use of endoprostheses approved by the U.S. FDA as a treatment of abdominal aortic aneurysms is considered investigational for certain clinical situations.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. No change to coverage.
03/04/2013	Coding revised
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Added “stent” to the title. Coverage eligibility unchanged.
01/01/2018	Coding update
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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06/06/2019 Medical Policy Committee review

06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/31/2020 Coding update

06/04/2020 Medical Policy Committee review

06/10/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2021

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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

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Code Type	Code
CPT	34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34714, 34715, 34716, 34808, 34812, 34813, 34820, 34833, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848 Codes added eff 1/1/2020: 34717, 34718
HCPCS	No codes
ICD-10 Diagnosis	I71.02, I71.3, I71.4, I71.8

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

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

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

- A. In accordance with nationally accepted standards of medical practice;

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

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

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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

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