# Endovascular Stent Grafts for Abdominal Aortic Aneurysms

**Policy #** 00035
Original Effective Date: 01/27/2003
Current Effective Date: 09/13/2021

*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 approved by the U.S. Food and Drug Administration (FDA) for the treatment of abdominal aortic aneurysms (AAAs) and used according to the U.S. FDA labeling to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) for the treatment of abdominal aortic aneurysms (AAAs) and used according to the U.S. FDA labeling will be considered when ANY of the following criteria are met:

- 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.

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 (FDA) through the premarket approval (PMA) process for the treatment of AAAs (Table 1). The original PMA dates are shown. Most stents have undergone device modification, name changes, and have approved supplements to the original PMA.

FDA product code MIH.

**Table 1. Abdominal Aortic Stent Grafts Approved by 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 | Endologix | 2012 | P120006 |
| Aorfix™‡ AAA Flexible Stent Graft System | Lombard Medical | 2013 | P110032 |
| Incraft®‡ AAA Stent Graft System | Cordis | 2018 | P150002 |

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.

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**Summary of Evidence**

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 cohort studies, and nonrandomized comparative 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 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 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 postsurgery, 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. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

# Supplemental Information

**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 Foundation and American Heart Association**

In 2011, the American College of Cardiology Foundation and the American Heart Association released an update to their 2005 guidelines on the management of abdominal aortic aneurysms (AAAs) that focused on the management of patients with peripheral artery disease. These guidelines made the following recommendations (see Table 2).

**Table 2. 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 American College of Cardiology and American Heart Association 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.

**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. 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 (SVS) 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.

Updated guidelines from the Society for Vascular Surgery support longer surveillance intervals for small AAAs and suggest the following surveillance schedule:

- For initial ultrasound screening aortic diameter >2.5 cm but < 3.0 cm, rescreening after 10 years
- For AAA 3.0 to 3.9 cm, imaging at 3 year intervals
- For AAA 4.0 to 4.9 cm, imaging at 12 month intervals
- For AAA 5.0 to 5.4 cm, imaging at 6 month intervals

This recommendation was based on studies evaluating aneurysm progression. In the United Kingdom small aneurysm study, surveillance intervals were used to minimize the likelihood of aneurysm expansion to greater than 5.5 cm between screening visits. As might be expected, the recommended intervals for surveillance were shorter for larger aneurysms and longer for smaller aneurysms. Surveillance was every 3 months for AAA 5.0 to 5.4 cm, every 12 months for AAA 4.5 to 4.9 cm, every 24 months for AAA 4.0 to 4.4 cm, and every 36 months for AAA 3.5 to 3.8 cm. In this study, less frequent surveillance was felt to be safe, and the suggested surveillance schedule resulted in a <1 percent chance of an aneurysm surpassing 5.5 cm in diameter between screening visits. These intervals are consistent with those used in the Multicentre Aneurysm Screening Study (MASS). Based largely upon these studies, multidisciplinary guidelines for the diagnosis and management of peripheral artery disease recommend surveillance every 6 to 12 months using

ultrasound or CT for aneurysms 4.0 to 5.4 cm in diameter but a less frequent interval (every two to three years) for aneurysms 3.0 to 4.0 cm in diameter, and every five years for aortic diameter between 2.6 to 2.9 cm. Recommendations for AAA surveillance schedule vary widely around the globe.

**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."

**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. 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 anteriorposterior 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 4.

**Table 4. 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 | Dec 2025 |
| NCT01726257[a] | Prospective, Multicenter, Single Arm Safety and Effectiveness Study of Endovascular Abdominal Aortic Aneurysm Repair Using the | 429 | Jun 2021 |

| | | | |
|---|---|---|---|
| | Nellix®‡ System: A Pivotal and Continued Access Study | | |
| NCT03966521 | The British Society of Endovascular Therapy ConformabLe EndoVascular Repair (BSET-CLEVAR) Registry | 200 | Jun 2021 |
| 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 |
| NCT02996396[a] | Multicenter, Observational, Registry to Assess Outcomes of Patients Treated With the CE Nellix®‡ System for Endovascular Abdominal Aortic Aneurysm Repair | 300 | Oct 2023 |
| 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) | 90 | May 2025 |
| NCT02489539[a] | Assessment of the GORE®‡ EXCLUDER®‡ Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms | 190 | Dec 2024 |
| NCT03180996[a] | A Prospective, Global, Multicentre, Real World Outcome Study of Fenestrated Endovascular | 160 | Sep 2030 |

| | | | |
|---|---|---|---|
| | Aneurysm Repair Using the Fenestrated Anaconda™‡ Device | | |
| NCT03446287 | Clinical Outcomes and Quality of Life Measures in Patients Treated With Open Surgical Repair for Complex Aortic Aneurysms | 150 | Dec 2030 |
| *Unpublished* | | | |
| 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 (updated 01/22/2020) |

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

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# Policy History

Original Effective Date: 01/27/2003
Current Effective Date: 09/13/2021

| | |
|---|---|
| 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 |

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|---|---|
| 01/31/2005 | Managed Care Advisory Council approval |
| 05/17/2005 | Medical Policy Committee review. Format revision. Policy statement changed from endoprostheses (i.e., endovascular grafts) as a treatment of abdominal aortic aneurysms (infrarenal abdominal or aortoiliac aneurysms) to: the use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms. Patient selection criteria expanded to include; "The use of FDA-approved endoprostheses as a treatment of abdominal aortic aneurysms may be considered medically necessary as a treatment of abdominal aortic aneurysms in any of the following clinical situations, consistent with the FDA-labeled indications for the AneurRx device." Investigational statement added to address non FDA-Approved devices and situations when patient selection criteria are not met. |
| 05/23/2005 | Managed Care Advisory Council approval |
| 07/07/2006 | Format revision; including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. |
| 08/02/2006 | Medical Director Review |
| 08/09/2006 | Medical Policy Committee approval. Rationale /Source and rationale updated. |
| 06/13/2007 | Medical Director review |
| 06/20/2007 | Medical Policy Committee approval. Coverage eligibility unchanged. Policy statement added for treatment of ruptured abdominal aortic aneurysm as investigational. |
| 08/06/2009 | Medical Policy Committee approval |
| 08/26/2009 | Medical Policy Implementation Committee approval. No change to coverage eligibility. |
| 07/01/2010 | Medical Policy Committee approval |
| 07/21/2010 | Medical Policy Implementation Committee approval. Changed coverage statement from investigational to eligible for coverage with criteria for ruptured abdominal aortic aneurysms. |
| 07/07/2011 | Medical Policy Committee review |
| 07/20/2011 | Medical Policy Implementation Committee approval. For clarification, added that the use of endoprostheses approved by the U.S. FDA as a treatment of abdominal aortic aneurysms is considered investigational for certain clinical situations. |
| 06/28/2012 | Medical Policy Committee review |
| 07/27/2012 | Medical Policy Implementation Committee approval. No change to coverage. |
| 03/04/2013 | Coding revised |

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 09/13/2021

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|---|---|
| 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. |
| 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. |
| 06/03/2021 | Medical Policy Committee review |
| 06/09/2021 | Medical Policy Implementation Committee approval. Revised the eligible for coverage section for clarity. Coverage eligibility unchanged. |
| 08/05/2021 | Medical Policy Committee review |
| 08/11/2021 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 09/13/2021

Next Scheduled Review Date: 08/2022

# 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 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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

CPT is a registered trademark of the American Medical Association.

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

| Code Type | Code |
|---|---|
| CPT | 34701, 34702, 34703, 34704, 34705, 34706, 34707, 34708, 34709, 34710, 34711, 34712, 34713, 34714, 34715, 34716, 34717, 34718, 34808, 34812, 34813, 34820, 34833, 34834, 34841, 34842, 34843, 34844, 34845, 34846, 34847, 34848 |
| HCPCS | No codes |

Endovascular Stent Grafts for Abdominal Aortic Aneurysms

Policy # 00035
Original Effective Date: 01/27/2003
Current Effective Date: 09/13/2021

| ICD-10 Diagnosis | I71.02, I71.3, I71.4, I71.8 |
|---|---|

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

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

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

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

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

**NOTICE:** 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.