ENDOVASCULAR STENT GRAFTS FOR ABDOMINAL AORTIC ANEURYSMS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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ENDOVASCULAR STENT GRAFTS FOR ABDOMINAL AORTIC ANEURYSMS
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**Description:**

Angioplasty:
Passage of a catheter through the blood vessel to decrease obstruction and restore blood flow. Percutaneous transluminal angioplasty (PTA) uses a balloon tipped catheter which is inserted to the area of disease and then inflated to compress the plaque against the vessel wall. Other devices that can be attached to the catheter are a laser and rotating shaver to ‘open’ the vessel.

Endovascular Graft (Stent) Placement:
Placement of a plastic or metal mesh tube into a blood vessel to maintain patency. Stent placement may be done following an angioplasty or as an alternative to an angioplasty. FDA-approved endovascular grafts for use in the abdominal aorta include:

- AneuRx® AAAdvantage Stent Graft
- Ancure® Aortoiliac System
- Aorfix™ AAA Flexible Stent Graft System
- EVT Abdominal Aortic Endovascular Grafting System
- Endologix AFX® endovascular system
- Endologix Powerlink®
- Gore® Excluder®
- Medtronic Talent® Abdominal Stent Graft System
- Medtronic Vascular Endurant® II AAA Stent Graft System
- Ovation™ Abdominal Stent Graft System
- Zenith® Flex AAA Endovascular Graft
- Zenith® Fenestrated AAA Endovascular Graft

**Endoleak:**
Leakage of the stent graft used for endovascular abdominal aortic aneurysm (AAA) repair.

- Type I endoleak results when the stent-graft fails to seal the vessel wall
- Type II endoleak is a leak within an aneurysm that is caused by flow of blood into the aneurysms sac from side branches of the aorta
- Type III endoleak occurs when the components of the stent-graft separate from each other
ENDOVASCULAR STENT GRAFTS FOR ABDOMINAL AORTIC ANEURYSMS
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Criteria:

➢ Endovascular stent placement with an FDA-approved endovascular graft for the treatment of abdominal aortic aneurysm (AAA) is considered medically necessary with documentation of ONE of the following:

1. Aneurysmal diameter greater than 5 cm
2. Aneurysmal diameter of 4-5 cm that has increased in size by 0.5 cm in the last six (6) months
3. Aneurysmal diameter of ≥ 3 cm with iliac aneurysm
4. Aneurysmal diameter that measures twice the size of the normal infrarenal aorta
5. Endoleak by imaging with ONE of the following:
   • Type I/III endoleak
   • Type II endoleak ≥ 6 months with AAA expansion

6. Ruptured abdominal aortic aneurysm with documentation of ALL of the following:
   • Individual sufficiently stable to undergo detailed computed tomography (CT) exam for anatomic measurements
   • Aneurysm anatomically appropriate for endovascular repair

7. Saccular aneurysm (any size)

➢ Angioplasty with endovascular stent placement for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

• Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery
• Treatment of aneurysms that do not meet the recommended threshold for surgery in individuals who are ineligible for open repair due to physical or anatomic limitations or other factors
ENDOVASCULAR STENT GRAFTS FOR ABDOMINAL AORTIC ANEURYSMS
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Resources:

Literature reviewed 06/23/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 05/28/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


2. InterQual® Care Planning Procedures. Endovascular Repair, Abdominal Aortic Aneurysm.