POLICY TITLE	ENDOVASCULAR GRAFTS FOR ABDOMINAL AORTIC ANEURYSMS
POLICY NUMBER	MP-1.090

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I. POLICY

Abdominal Aortic Aneurysm Repair

The use of endoprostheses approved by the U.S. Food and Drug Administration (FDA) may be considered **medically necessary** as a treatment of abdominal aortic aneurysms in any of the following clinical situations:

- An aneurysmal diameter greater than 5.0 cm;
- An aneurysmal diameter of 4-5.0 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 abdominal aortic aneurysm.

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

- The patient must be sufficiently stable to undergo detailed computed tomography (CT) examination for anatomic measurements,
- The aneurysm should be anatomically appropriate for endovascular repair, and
- Specialized personnel should be available.

The use of endoprostheses approved by the FDA as a treatment of abdominal aortic aneurysms is considered **investigational** for 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.

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There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for the above indications.

Cross-reference:
MP-1.132 Endovascular Stent Grafts for Disorders of the Thoracic Aorta

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO- Refer to FEP Medical Policy Manual MP-7.01.67 Endovascular Grafts for Abdominal Aortic Aneurysms. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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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.[1-4]

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.

REGULATORY STATUS

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 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. FDA product code MIH.

Table 1. Abdominal Aortic Stent Grafts Approved by 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	TriVascular	2012	P120006
Aorfix™ AAA Flexible Stent Graft System	Lombard Medical	2013	P110032

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

IV. RATIONALE

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SUMMARY OF EVIDENCE

For individuals who have AAAs eligible for open repair who receive endovascular stent grafts, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are overall survival, 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 EVAR is associated with an early reduction in mortality, outcomes at 5 years or longer have shown 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 and systematic reviews of RCTs. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. For patients with ruptured AAAs,

evidence from 4 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. Relevant outcomes are overall survival, 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 sufficient to determine that the technology is unlikely to improve the net health outcome.

V. DEFINITIONS

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AORTA is the largest artery in the body, originating from the left ventricle of the heart and extending down to the abdomen, where it branches off into two smaller arteries (the common iliacs). The aorta distributes oxygenated blood to all parts of the body through the systemic circulation. It is usually divided into five segments/sections:

- Ascending aorta—the section between the heart and the arch of aorta
- Arch of aorta—the peak part that looks somewhat like an inverted "U"
- Descending aorta—the section from the arch of aorta to the point where it divides into the common iliac arteries ○ Thoracic aorta—the half of the descending aorta above the diaphragm ○ Abdominal aorta—the half of the descending aorta below the diaphragm

STENT refers to any material or device used to hold tissue in place, to maintain open blood vessels, or to provide support for a graft or anastamoses while healing is taking place.

THORACIC refers to the chest or thorax.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and

providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®							
34701	34702	34703	34704	34705	34706	34708	34709
34710	34711	34714	34715	34716	34808	34812	34813
34820	34830	34831	34832	34833	34834	34839	34841
34842	34843	34844	34845	34846	34847	34848	36200
36245							

ICD-10-CM Diagnosis Codes	Description
I71.3	Abdominal aortic aneurysm, ruptured
I71.4	Abdominal aortic aneurysm, without rupture

IX. REFERENCES

TOP

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and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease) endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. J Am Coll Cardiol. Mar 21 2006;47(6):1239-1312. PMID 16545667

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X. POLICY HISTORY

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MP 1.090	**CAC 5/27/03**
	CAC 5/31/05
	CAC 2/28/06
	CAC 2/27/07
	CAC 1/29/08 Consensus
	CAC 11/25/08
	CAC 11/24/09 Consensus
	CAC 11/30/10 Consensus
	CAC 2/28/12 Adopting BCBSA. Added statement indicating use of endovascular grafts for treatment of ruptured abdominal aortic aneurysm is medically necessary along with list of factors for consideration. Other medically necessary indications are unchanged. Two investigational statements added -- Treatment of smaller aneurysms that do not meet the current recommended threshold for surgery and use in patients who are ineligible for open repair due to physical limitations or other factors, even if the aneurysm meets the recommended threshold for surgery. Extracted information related to use of endovascular grafts for thoracic aortic aneurysms or dissections and use of wireless pressure sensors for endovascular aneurysm repair from this policy and two separate policies were created. See cross references.

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	CAC 3/26/13 Consensus review, no changes to policy statement, references updated. Codes reviewed.
	CAC 1/28/14 Consensus. No change to policy statements. References updated. Rationale section added.
	11/10/14-Admin review- Codes reviewed, no change in policy statements.
	CAC 1/27/15 Consensus review. The 2nd policy statement was revised to clarify situations that do not meet the criteria in the 1st policy statement that would be considered investigational. References and rationale updated.
	01/2015-New 2015 codes added to policy
	08/12/2015-Add on codes 34808, 34813 and 34826 added to policy.
	CAC 1/26/16 Consensus review. No change to policy statements. References and rationale updated.
	Admin update 1/1/17: Product variation section reformatted.
	11/29/16 Consensus review. No change to policy statements. Background, rationale and references updated. Variations reformatted. Coding reviewed/updated.
	12/19/17 Consensus review. Coding reviewed. New Codes 34701-34706, 34709-34711, and 34714-34716 added plus end dated codes 34800, 34801-34805, 34825-34826, and 75952-75952 removed; effective 1/1/18.
	9/19/18 Consensus review. No change to the policy statements. Background and references updated. Rationale revised.
	4/15/2019 Admin Coding Update. Codes 34808 & 36245 added to policy.

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