MEDICAL POLICY

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

Effective Date:	11/1/2023

I. POLICY

Abdominal Aortic Aneurysm Repair

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

- An aneurysmal diameter greater than 5.0 cm **OR**
- An aneurysmal diameter of 4.0 -5.0 cm that has increased in size by 0.5 cm in the last 6 months; **OR**
- An aneurysmal diameter that measures twice the size of the normal infrarenal aorta; **OR**
- A ruptured abdominal aortic aneurysm; **OR**
- Treatment of aneurysms that 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 approved by the FDA is considered **investigational** for treatment of smaller abdominal aortic aneurysms that do not meet the current recommended threshold for surgery, as there is insufficient evidence to support a general 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

POLICY GUIDELINES

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

- The member 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.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. 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. 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.

In about 10% of AAA, there is an associated iliac artery aneurysm (IAA). Isolated iliac artery aneurysms are uncommon, comprising less than 2% of all abdominal aneurysmal disease. IAA is defined as a dilatation of the iliac artery of 1.5-fold the normal diameter. Despite their rarity, several reports have suggested that isolated iliac artery aneurysms have a high risk of rupture, with an associated high mortality rate of up to 80%. Most of these aneurysms remain asymptomatic. Consequently, diagnosis of iliac artery aneurysms is usually made incidentally during ultrasound, CT scanning, or angiography.

Based on results of retrospective reviews of ruptured IAA and expert consensus opinion, an IAA diameter of 3 cm is the traditional threshold above which asymptomatic iliac aneurysm repair is recommended.

Utilizing endovascular technique, has significantly decreased in-operative morbidity and mortality as well as, fewer complications and a shorter length of hospital stay. Open surgical techniques for repair of IAA, although usually straightforward, can be complicated by difficult exposures, blood loss, morbidity, and mortality.

In December 2022, the American College of Cardiology and the American Heart Association published the “Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines.” Regarding Open Versus Endovascular Repair of AAA, a 2a B-NR recommendation states “In patients with nonruptured AAA and a high perioperative risk, EVAR is reasonable to reduce the risk of 30-day morbidity, mortality, or both.” The document goes on to explain that “EVAR-2 (UK Endovascular Aneurysm Repair 2) was an RCT that evaluated outcomes of EVAR in high-risk patients. Patients were enrolled if they were determined to be unfit for open surgery, with fitness assessed using cardiac, respiratory, and renal criteria. In these patients, the trial initially showed that EVAR did not improve survival compared with the control of no intervention; however, more than a decade later, those treated with EVAR had significantly lower aneurysm-related mortality (hazard ratio, 0.55; 95% CI, 0.34–0.91). Contemporary analyses of outcomes in high-risk patients show that perioperative death after EVAR has markedly decreased (eg, 9% in EVAR-2 versus 1.9% in the ACS national registry). Furthermore, in evaluating a propensity-matched Medicare population, postoperative complications that are more likely to affect high-risk patients, such as myocardial infarction, pneumonia, acute renal failure, and need for dialysis, were all significantly less likely to occur after infrarenal EVAR compared with open repair.

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
Incraft® AAA Stent Graft System	Cordis	2018	P150002
TREO® Abdominal Stent-Graft System	Bolton Medical, Inc.	2020	P190015
AltoTM Abdominal Stent Graft System	Endologix, Inc.	2020	P120006/S031

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 randomized controlled trials (RCTs), systematic reviews of RCTs and cohort studies, and nonrandomized comparative 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 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 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 patient's 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.

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 o 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 anastomoses 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 health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross 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:

Procedure Codes							
34701	34702	34703	34704	34705	34706	34707	34708
34709	34711	34712	34713	34714	34715	34716	34717
34718	34808	34812	34813	34820	34833	34834	34839
34841	34842	34843	34844	34845	34846	34847	34848
36200	36245						

ICD-10-CM Diagnosis Codes	Description
I71.00	Dissection of unspecified site of aorta
I71.02	Dissection of abdominal aorta
I71.03	Dissection of thoracoabdominal aorta
I71.30	Abdominal aortic aneurysm, ruptured, unspecified
I71.31	Pararenal abdominal aortic aneurysm, ruptured
I71.32	Juxtarenal abdominal aortic aneurysm, ruptured
I71.33	Infrarenal abdominal aortic aneurysm, ruptured
I71.40	Abdominal aortic aneurysm, without rupture, unspecified
I71.41	Pararenal abdominal aortic aneurysm, without rupture
I71.42	Juxtarenal abdominal aortic aneurysm, without rupture
I71.43	Infrarenal abdominal aortic aneurysm, without rupture
I71.50	Thoroacoabdominal aortic aneurysm, ruptured, unspecified
I71.51	Supraceliac aneurysm of the abdominal aorta
I71.52	Paravisceral aneurysm of the abdominal aorta, ruptured
I71.60	Thoracoabdominal aortic aneurysm, without rupture, unspecified
I71.61	Supraceliac aneurysm of the abdominal aorta, without rupture
I71.62	Paravisceral aneurysm of the abdominal aorta, without rupture
I71.9	Aortic aneurysm of unspecified site, without rupture
I72.3	Aneurysm of iliac artery

Covered when medically necessary for a diagnosis from Table 2

Procedure Codes							
34710*	34830	34831	34832				

Table 2

ICD-10-CM Diagnosis Codes	Description
I71.00	Dissection of unspecified site of aorta
I71.02	Dissection of abdominal aorta
I71.03	Dissection of thoracoabdominal aorta
I71.30	Abdominal aortic aneurysm, ruptured, unspecified
I71.33	Infrarenal abdominal aortic aneurysm, ruptured

I71.40	Abdominal aortic aneurysm, without rupture, unspecified
I71.43	Infrarenal abdominal aortic aneurysm, without rupture
I71.9	Aortic aneurysm of unspecified site, without rupture
I72.3*	Aneurysm of iliac artery

* This is the only procedure code that includes ICD10 I72.3.

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.090	**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.
	7/29/2019 Consensus review. Policy statement unchanged. References updated.
	1/1/2020 Admin Update. Added new codes 34717 & 34718.
	2/21/2020 Consensus review. Policy statement unchanged. References reviewed. Coding reviewed.
	1/19/2021 Consensus review. Policy statement unchanged. Background and references updated.
	08/01/2022: Administrative update. ICD10 codes updated
	08/05/2022: Consensus review Policy statement unchanged. Updated background to include iliac artery aneurysms. Codes 34712 and 34713 added. ICD10 code I72.3 added. References update.
	5/18/2023 Minor review. Moved statement "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" from INV to MN. Updated background, references. No coding changes.

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