

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: MP.047
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SUBJECT: Endovascular Stent for Abdominal Aortic Aneurysm
INDEX TITLE: Medical Management
ORIGINAL DATE: December 2004

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()		POS ()		PPO ()	
Fully Insured ()		Self-funded/ASO ()		HSA ()	
Medicare Select ()		Medicare Supplement ()			
DPW-MA:					
Health Choices ()			Voluntary ()		All (X)
CMS-MA:					
OH ()		WV ()		PA ()	All (X) Other ()
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X)	All ()
PID-CHIP:					
Free ()			Sub ()		All (X)
APPLICABLE TO:					
Community Care ()		Work Partners ()			

I. POLICY

It is the policy of UPMC Health Plan to cover endovascular stent for abdominal aortic aneurysm when it is medically necessary and covered under the member's benefit plan.

UPMC Health Plan recognizes endovascular stenting for abdominal aortic aneurysm (AAA) as appropriate and consistent with good medical practice when performed for members having morphology suitable to endovascular repair. Coverage will be considered after review on an individual basis for the specific indications detailed in this policy.

All denials are based on medical necessity and appropriateness as determined by a UPMC Health Plan Medical Director (Medical Director).

II. DEFINITIONS

Abdominal Aortic Aneurysm (AAA) is defined for the purpose of this policy as a focal dilation of the vessel equal to or greater than 150% of the size of the non-dilated proximal aortic segment.

IDE- Investigational Device Exemption

III. PURPOSE

The purpose of this policy is to define the criteria for Endovascular Stent for Abdominal Aortic Aneurysm.

IV. SCOPE

This policy applies to various UPMC Health Plan Departments as indicated by the Benefit and Reimbursement Committee. These include, but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. PROCEDURE

A. Medical Description

The conventional management of a clinically significant AAA consists of surgical excision with placement of a sutured woven graft. The existing standard of care is elective open surgical repair, when warranted by the size, symptoms, or rate of expansion of the aneurysm. Surgical excision is associated with a perioperative mortality rate of 4%, which may rise to 80% in symptomatic members. Due to this high mortality rate, endovascular stents have been investigated as a minimally invasive, catheter-based alternative. These devices are deployed across the aneurysm such that the aneurysm is effectively "excluded" from the circulation.

Candidates for endovascular repair of infrarenal AAA must be selected carefully based on the vascular anatomy. The procedure involves the placement of the device within the lumen of the aorta and usually the iliac(s) via a femoral artery incision using a specialized delivery system under fluoroscopic guidance. Once the device is in position, it is released from the carrier and springs open within the aneurysm. A balloon is often inflated to fully expand the device. The device is long enough to overlap onto normal vessels proximal and distal to the aneurysm, but occasionally endovascular leaks necessitate further intervention. Leaks around the top or bottom edges of the endograft are usually treated by further ballooning within the graft or by placement of additional proximal or distal extension prostheses.

B. Specific Indications

Endovascular stenting for AAA may be considered medically necessary for members with aneurysms having morphology suitable to endovascular repair when any of the following criteria are met:

1. Any AAA of diameter equal to or greater than twice the diameter of the non-dilated proximal aortic segment.
2. Any AAA with documented expansion in size in twelve (12) months.

3. Any symptomatic or ruptured AAA. The primary symptoms are tenderness on palpation and/or pain that may occur in the back, flank, groin, or abdomen. Other symptoms are related to compression of nearby structures such as veins or ureters.
4. Any AAA with an aneurysmal iliac component.

Note: The above measurements should be obtained by CT and represent the minor axis on the axial CT or any measurement perpendicular to the line of flow on a 3D reconstruction.

C. Limitations

1. Endovascular stent for AAA must be performed by a physician with credentialed experience in this technology.
2. The endovascular graft must be FDA approved for the treatment of AAAs,
OR
Is a device with a Category B IDE number that is deemed to be reasonable and medically necessary as per regulatory and other applicable guidelines.

D. Information Required for Review

In order to assess medical necessity for endovascular stent for AAA, adequate information must be furnished by the treating physician. Necessary documentation includes the following:

1. The physician's evaluation of the member's condition to determine medical necessity of the procedure, including all comorbid conditions.
2. Clinical documentation supporting eligibility for procedure.
3. Type/brand of graft to be used.

For IDE: All requirements for IDE exemption should be followed.

E. Review Process

1. The Medical Management staff assigned to review obtains the clinical information to determine if there is adequate clinical information. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

N/A

G. References

1. ECRI, Inc. Technology Assessment Report. Endovascular grafts for prophylactic abdominal aortic aneurysm repair. Published 3/2004. Plymouth Meeting PA.
2. U.S. Food and Drug Administration, Center for Devices and Radiologic Health. AneuRx Stent Graft System. PMA No. P990020. Rockville, MD: FDA; September 28, 1999. <http://www.fda.gov/cdrh/pdf/p990020.html>
3. U.S. Food and Drug Administration, Center for Devices and Radiologic Health. ANCURE Aortoiliac System. PMA No. P990017/S030. Rockville, MD: FDA; April 24, 2002. <http://www.fda.gov/cdrh/pdf/p990017s030.html>.
4. Department of Health and Human Services Federal Register, CMS-9020-N, Vol 69 No 59, 3-26-04
5. Highmark Medicare Services,. Local Coverage Policy number S-138-A, Endovascular Repair of Abdominal Aortic Aneurysm, Retired 1/1/04
<http://www.hgsa.com/professionals/policy/s138.html>
6. Highmark Medicare Services, Investigational Device Exemptions (IDEs) Requests, Revised December 13, 2006, <http://www.highmarkmedicareservices.com/trials-ide/ide.html>
7. Center for Medicare and Medicaid Services, Article for Investigational Device Exemption (IDEs) and Clinical Trials,
http://www.cms.hhs.gov/med/viewarticle.asp?article_id=38453&article

Disclaimer:

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