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1.0 Description of the Procedure, Product, or Service

The aorta is a large blood vessel that projects upward from the heart and then arches downward, traveling through the chest (thoracic aorta) and into the abdomen (abdominal aorta). An aortic aneurysm is a widening or bulging of a weakened or damaged portion of the aorta. The pressure of blood pressing against the weakened part of the blood vessel eventually forces the bulge to expand outward. Most aortic aneurysms occur in the abdominal portion. A thoracic aneurysm is somewhat less common, but is considered a more morbid condition. Untreated patients with thoracic aortic aneurysms have a two-year survival rate of less than 30%, with half of all deaths caused by aneurysm rupture. Isolated iliac aneurysms are unusual in the absence of a proximal aortic aneurysm, accounting for less than 1% of peripheral arterial aneurysms.

The traditional standard treatment for an aortic aneurysm is open surgical repair with graft replacement of the affected segment. Endovascular repair has been proposed as a less invasive alternative to open surgical treatment. The endovascular graft or stent is introduced by a catheter through the femoral artery and passed into the aorta. The device is deployed across the aneurysm so that the aneurysm is excluded from the circulatory system. The endovascular graft provides an alternative conduit for blood flow and, in theory, protects the aneurysm sac from abrupt pressure changes that cause further enlargement of the aneurysm and possible rupture.

Although initial endovascular grafting may be successful, a small risk of aneurysm rupture due to late failure of the endograft still remains. Periodic monitoring for endoleak and sac dilation is done with contrast enhanced CT scans. In order to reduce the risk of rupture and the frequency of CT scanning, endosensors are being developed that will provide for monitoring of aortic aneurysm pressure after endovascular repair. A sensor device is inserted during the same procedure as the endovascular stent graft and is positioned next to the graft within the aneurysm sac. Pressure measurements are transmitted via radiofrequency to a device that is held over the recipient's body.

1.1 Medical Term Definition

Stent: an insert placed into a tubular structure to provide support when the two tubular structures are being joined. Stents help keep a vessel open. Stents have other uses as well, such as those used to keep skin grafts in place.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

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3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Endovascular stent grafts for aortic aneurysms are determined to be medically necessary when the following medical criteria have been met:

a. Endovascular stent grafts for abdominal aortic aneurysms are covered when any of the following criteria are met:

   1. the diameter of the abdominal aortic aneurysm measures equal to or greater than 5 cm.

   2. the aneurysmal diameter of 4-5 cm has increased in size by 0.5 cm in the last six (6) months.

   3. the abdominal aortic aneurysm measures twice the diameter of the normal aorta at the infrarenal neck.

b. Endovascular stent grafts for thoracic aortic aneurysms may be considered medically necessary for the treatment of descending thoracic aortic aneurysms of 23-37 mm of inner aortic diameter.

c. Endovascular stent grafts for iliac aneurysms are covered for iliac artery aneurysms greater than 3 cm in recipients with appropriate aortoiliac anatomy.

3.3 Policy Guidelines

a. Endovascular repair can be done safely and recovery in the intensive care unit is rarely required with patients usually discharged home sooner than patients undergoing open surgical repair. Major cardiopulmonary complications also occur less frequently. In addition, there appears to be a decrease in blood transfusion requirements, hospital length of stays and intensive care monitoring. Patients generally return to pre-intervention levels of activity more rapidly. Current recommendations for the repair of AAA in intermediate to high surgical risk recipients support the use of endovascular repair.

b. The indications for the elective surgical repair of aortic aneurysms are based on estimates of the prognosis of the untreated aneurysm balanced against the morbidity and mortality of the intervention. This significant morbidity and mortality makes definitive patient selection criteria for repair of thoracic aneurysms

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difficult. Several authors have recommended an individual approach based on balancing the patients' calculated risk of rupture with their anticipated risk of postoperative death or paraplegia. However, in general, surgical repair is considered in patients with adequate physiologic reserve when the thoracic aneurysm measures from 5.5 to 6 cm in diameter, or in patients with smaller symptomatic aneurysms. Initial case series of endovascular repair have reported promising results. The data are sufficient to demonstrate that the use of endovascular stent grafts in the thoracic aorta are associated with equivalent or improved outcomes compared to open surgical repair.

c. The GORE TAG Thoracic Endoprosthesis received U.S. Food and Drug Administration (FDA) approval through the Premarket Approval (PMA) process in March, 2005, for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy including: adequate iliac/femoral access, aortic inner diameter in the range of 23-37 mm and greater than or equal to 2 cm non-aneurysmal aorta proximal and distal to the aneurysm.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

a. the recipient does not meet the eligibility requirements listed in **Section 2.0;**
b. the recipient does not meet the medical necessity criteria listed in **Section 3.0;**
c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

a. The use of endovascular stent grafts is considered investigational for all other indications not noted in **Subsection 3.2** including the treatment of thoracic aortic arch aneurysms or aortic dissections. The use of non-FDA approved endovascular stent graft devices is also considered investigational.

b. Implanted intrasac pressure sensors for detection of endoleaks in the aneurysmal sac following endovascular repair are not covered because they are considered investigational.

4.3 Policy Guidelines

At this time, there are inadequate published data on implantable intrasac pressure sensors to permit conclusions concerning long-term safety and efficacy of this technology.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for endovascular stent grafts for aortic aneurysm.

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5.2 Prior Approval Requirements

The provider(s) shall submit to DMA's designee the following:

a. the prior approval request; and
b. all health care records and any other records that support the NCHC recipient has met the specific criteria in **Subsection 3.2** of this policy.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

a. meet NCHC qualifications for participation;
b. be currently enrolled with NCHC; **AND**
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers shall comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
7/1/ 2010	**Throughout**	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**
9/30/2011	Throughout	Policy Termination

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Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes				
0078T	0079T	0080T	0081T	33880
33881	33883	33884	33886	33889
33891	34800	34802	34803	34804
34805	34806	34808	34812	34813
34820	34825	34826	34900	

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.

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