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## 1.0 Description of the Procedure, Product, or Service

The success of coronary artery angioplasty and stenting prompted interest in applications of catheter-based endovascular intervention in carotid artery disease. Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (CEA), currently considered the standard treatment for recipients with significantly obstructing carotid atherosclerosis (stenosis). Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices through the femoral artery and into the carotid artery. The procedure typically takes 20–40 minutes. Interventionalists almost uniformly use a distally placed embolic protection device (EPD) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Carotid angioplasty rarely is performed without stent placement.

Proposed advantages of CAS over CEA include:

- a. General anesthesia is not used (although CEA can be performed under local/regional anesthesia).
- b. Cranial nerve palsies are infrequent sequelae.
- c. Simultaneous procedures may be performed on the coronary and carotid arteries.

The U.S. Food and Drug Administration (FDA) approved carotid artery stents and EPDs from various manufacturers:

- a. ACCULINK™ and RX ACCULINK™ carotid stents and ACCUNET™ and RX ACCUNET™ cerebral protection filters, Guidant Corp. (approved August 2004);
- b. Xact® RX carotid stent system and Emboshield® embolic protection system, Abbott Vascular Devices (approved September 2005);
- c. Precise® nitinol carotid stent system and AngioGuard™ XP and RX emboli capture guidewire systems, Cordis Corp. (approved September 2006);
- d. NexStent® carotid stent over-the-wire and monorail delivery systems, Endotex Interventional Systems; and FilterWire EZ™ embolic protection system, Boston Scientific Corp. (approved October 2006); and
- e. ProtégéRx® and SpideRx®, ev3 Inc, Arterial Evolution Technology. (approved January 2007)

Each FDA-approved carotid stent system is indicated for combined use with an EPD to reduce risk of stroke in patients considered to be at increased risk for periprocedural complications from CEA who are symptomatic with >50% stenosis, or asymptomatic with >80% stenosis. Patients are considered at increased risk for CEA complications if affected by any item from a list of anatomic features and comorbid conditions included in each stent system's Information for Prescribers. CAS with these devices for patients outside those indications is an off-label use.

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FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the RX (rapid exchange) devices designed for more rapid stent and filter expansion. The Precise® and AngioGuard™ devices were studied in a randomized, controlled trial (the SAPPHERE trial; refer to Rationale section). Other devices were approved based on uncontrolled, single-arm trials or registries, and comparison to historical controls. The FDA has mandated postmarketing studies for these devices, including longer follow-up for patients already reported to the FDA and additional registry studies, primarily to compare outcomes as a function of clinician training and facility experience. Each manufacturer's system is available in various configurations (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

## 2.0 Eligible Recipients

### 2.1 General Provisions

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

## 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

Carotid angioplasty with associated stenting and embolic protection may be covered under the NC Health Choice Program when it is considered medically necessary in recipients with the following:

- a. 50-99% stenosis (NASCET measurement);
- b. Symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days, symptom duration less than 24 hours or non disabling stroke; **AND**
- c. Anatomic contraindications for carotid endarterectomy such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy.

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### 3.3 Other Medical Policy Guidelines

Endovascular (CAS) or surgical intervention (CEA) for carotid artery disease trades procedure-related harms of stroke and death for the benefit of reduced stroke risk over subsequent years—their balance determines whether either intervention will result in a net clinical benefit. That balance has been scrutinized for CEA although not for CAS; accordingly results from trials of CEA must be applied.

There is sufficient evidence to conclude that periprocedural death/stroke rates exceed those established as clinically acceptable and associated with a net clinical benefit as defined by pivotal trials of CEA. There is limited evidence but clinical rationale to suggest CAS may be beneficial in the group of recipients with unfavorable anatomy; however, given the small number of recipients for whom evidence is available the accompanying uncertainty is large. Thus, there is insufficient evidence to draw data-driven conclusions regarding recipients with unfavorable anatomy.

A substantive body of evidence does not support use of CAS in carotid artery disease. However, based on limited data, clinical input, the chain of indirect evidence, and an unmet medical need, CAS may be considered a reasonable option.

### 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

Carotid angioplasty with or without associated stenting and embolic protection is considered investigational for all other indications.

### 5.0 Requirements for and Limitations on Coverage

#### 5.1 Prior Approval

Prior approval is not required for carotid angioplasty with or without associated stenting and embolic protection.

### 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;

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- 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 must 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:**

<b>Date</b>	<b>Section Revised</b>	<b>Change</b>
<b>July 1, 2010</b>		Policy Conversion: Implementation of Session Law 2009-451, <b>Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”</b>
	Throughout	Terminate policy

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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 Code(s)
37125
37126

HCPCS Code(s)
0075T
+0076T

**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.