

UPMC Insurance Services Division POLICY AND PROCEDURE MANUAL

POLICY NUMBER MP.046
REVISION DATE: 01/12
ANNUAL APPROVAL DATE: 02/12
PAGE NUMBER: 1 of 8

SUBJECT: Extracranial Carotid Angioplasty with Stenting
INDEX TITLE: Medical Management
ORIGINAL DATE: December 2004

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

COMMERCIAL	CMS-MA	DPW-MA	ANCILLARY
HMO ()	OH ()	Health Choices /PH (X)	UPMC Dental Adv. ()
PPO ()	WV ()	Voluntary (X)	UPMC Vision Adv. ()
Fully Insured ()	PA ()	Health Choices/BH ()	COBRA ()
Self-funded/ASO ()	All (X)	All ()	FSA ()
Indiv. Product ()	HMO (X)	WORKPARTNERS	HSA ()
All (X)	PPO (X)	Commercial WC ()	HRA ()
PID-CHIP	ISNP (X)	Disability Svcs/TPA ()	HIA ()
CHIP (X)	DSNP (X)	Health Promotion ()	All ()
	Part D ()	All ()	
	All ()		

I. POLICY

It is the policy of UPMC Insurance Services Division to cover extracranial carotid angioplasty with stenting when it is medically necessary and covered under the member's specific benefit plan.

UPMC Insurance Services Division recognizes carotid artery stenting as appropriate and consistent with good medical practice when performed for members at high risk for adverse events from carotid endarterectomy. 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 Insurance Services Division Medical Director (Medical Director).

This policy is applicable to Extracranial Carotid Artery Stenting only. This includes carotid lesions at the base of the skull, since these are considered extracranial.

(Refer to MP.014 Intracranial Stenting).

II. DEFINITIONS

North American Symptomatic Carotid Endarterectomy Trial (NASCET)

Methodology - The degree of stenosis is determined by calculating the ratio of the diameter of the artery at the point of maximal narrowing to the normal diameter distal to the stenosis (well beyond the carotid artery bulb).

III. PURPOSE

The purpose of this policy is to define the medical necessity indications for extra cranial carotid angioplasty with stenting.

IV. SCOPE

This policy applies to various UPMC Insurance Services Division 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

Embolic Protection Devices- a separate catheter-based device designed to catch fatty atherosclerotic plaque particles and small blood clots that may dislodge during extracranial carotid artery stenting (CAS) and travel within the bloodstream, causing a stroke by blocking another vessel.

Extracranial carotid artery stenting (CAS) is a catheter-based procedure that has emerged as a minimally invasive alternative to carotid endarterectomy. CAS is intended to prevent stroke in members with carotid artery disease who are at high risk of surgical adverse events due to comorbidities.

Stents used for carotid applications are expandable scaffolds deployed in the vessel using balloon expansion or self-expansion to widen the stenotic region. Under fluoroscopic guidance, delivery of a balloon to the stenotic region is possible using a series of guide wires and sheaths/catheters introduced through the femoral artery and manipulated to reach the carotid artery. Inflation of the balloon compresses the plaque and stretches the arterial wall. Placement of a carotid stent helps to maintain the vessel's diameter and prevent re-stenosis. Vascular closure devices made of absorbable material that do not require subsequent removal effectively close the wound and reduce the risk of bleeding at the surgical site.

Because intervention in the carotid arteries has the potential to dislodge fatty plaque particles and small blood clots that could travel and block other blood vessels in the brain, several stent manufacturers have developed embolic protection devices to be used in conjunction with CAS.

B. Specific Indications

Extracranial carotid angioplasty with stenting is considered medically necessary for any of the following:

1. Members who are at High Risk for Adverse Events from Carotid Endarterectomy (CEA), who require carotid revascularization and the member meets at least one (1) the following criteria:

- The procedure is performed using the U.S. Food and Drug Administration (FDA) approved CAS systems/devices and in conjunction with an FDA approved embolic protection device

AND

- Members **with** hemispheric neurological **symptoms** in the ipsilateral carotid artery distribution and $\geq 50\%$ stenosis of the common or internal carotid artery confirmed by angiographic measurement using NASCET methodology;

OR

Members who are at high surgical risk **without** neurological **symptoms** and $\geq 80\%$ stenosis of the common or internal carotid artery confirmed by angiographic measurement using the NASCET methodology.

High Risk Factors for carotid endarterectomy include **any** of the following:

- Congestive heart failure (CHF) Class III /IV
- Left ventricular ejection fraction (LVEF) $< 30\%$
- Unstable angina
- Contralateral carotid occlusion
- Recent myocardial infarction (MI)
- Previous carotid endarterectomy with recurrent stenosis
- Prior radiation treatment to the neck
- Contralateral laryngeal nerve palsy
- Requirement for combined coronary and carotid vascularization,
- Severe pulmonary dysfunction,
- Radical neck surgery
- Open heart surgery within 6 months
- Clearly documented as not a surgical candidate
- Chronic obstructive lung disease
- Chronic renal insufficiency with creatinine above 2.5

OR

2. The procedure is performed as part of Investigational Device Exemption (IDE) Clinical Trials

OR

As part of an FDA Approved Post Approval Studies and the member meets one (1) the following:

- Members who are at high risk and **with** neurologic **symptoms** and carotid artery stenosis between 50 and 70%.

OR.

- Members who are at high risk **without** neurological **symptoms** and $\geq 80\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram; (Refer to Clinical Trial and Experimental and Investigative Services policies)

OR

3. The member has carotid lesions that, due to their anatomic location, are difficult to approach surgically.

C. Limitations

1. If the use of an embolic protection device is not possible during an attempted CAS procedure, the procedure should be abandoned due to the risk of adverse events without embolic protection.
2. Carotid angioplasty with stenting **must** be performed by a physician with training and experience in this technology;

AND

Facilities at which this procedure is performed must have written FDA approvals for Clinical trials or must have written affidavits approved by Centers for Medicare and Medicaid Services (CMS) attesting that they have met the minimum facility standards.

(Refer to Clinical Trials policy)

3. **Not Covered:**

- Vertebral artery angioplasty with/without stenting (due to the lack of scientific evidence).

4. **Contraindications:**

- Members in whom anti-coagulant and/or anti-platelet therapy is contraindicated,
- Members with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath, embolic protection or stent system,
- Members with known sensitivity to nickel-titanium,
- Members with uncorrected bleeding disorders,
- Members with disabling stroke (modified Rankin scale >3). – this is a relative contraindication,
- Atrial fibrillation (relative contraindication).

D. Information Required for Review

In order to determine medical necessity for carotid angioplasty with stent, adequate information must be furnished by the treating physician. Necessary documentation includes all the following:

1. The physician's evaluation of the member's condition, including all comorbid conditions.
2. Documentation of neurological symptoms including:
 - History of transient ischemic attack,
 - Focal ischemia producing a non-disabling stroke,
 - Transient monocular blindness (amaurosis fugax).

3. Documentation supporting high risk for carotid endarterectomy. High risk for endarterectomy has to be documented by an appropriately credentialed physician.
4. Degree of carotid artery stenosis measured by doppler ultrasound or carotid artery angiography
5. Name of stent and embolic device and documentation of FDA approval.

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

Medical Assistance and CHIP Products

Clinical trials and investigational devices (IDE) are not covered for these products

G. Records Retention

Records Retention for UPMC Insurance Services Division documents, regardless of medium are provided within the UPMC Health System Policy for Records Retention, Management and Retirement, and as indicated in the UPMC Insurance Services Division Policy and Procedure for Records Retention.

H. References

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