

Policy: MP150

Section: Medical Benefit Policy

Subject: Carotid Artery Stent

I. Policy: Carotid Artery Stent

II. Purpose/Objective:

To provide a policy of coverage regarding Carotid Artery Stent

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Carotid stents are positioned at the site of carotid stenotic or occlusive lesions to enhance primary patency following percutaneous transluminal angioplasty.

INDICATIONS:

Coverage is limited to the use of FDA approved carotid stents for FDA approved indications when the following criteria are met:

- Documented evidence of a reference vessel diameter within the range of 4.0mm and 9.0mm; **and one of the following:**
 - Member is at high risk* for carotid endarterectomy (CEA) with one of the following:
 - symptomatic carotid stenosis greater than 50% or more by angiogram or 70% or more by ultrasound; **or**
 - asymptomatic carotid artery stenosis of 60% or more by angiogram or 70% or more by ultrasound.
- or**
- Members who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq 80\%$, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201)

*CMS defines high risk as those “having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and who would be poor candidates for CEA in the opinion of a surgeon”.

Significant comorbid conditions include but are not limited to:

- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) < 30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis ;
- prior radiation treatment to the neck; and
- other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Centers for Medicare and Medicaid Services Decision Memo for Carotid Artery Stenting (CAG-00085R0)

EXCLUSIONS: Carotid artery stenting will be limited to the placement of an FDA-approved carotid stent for an FDA – approved indication when furnished in accordance with FDA- approved protocols governing post-approval studies. Placement of carotid stents not meeting these requirements is considered **experimental, investigational or unproven** and is **NOT COVERED**.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Carotid Artery Stent

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

37215 transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection

37216 transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection

37217 transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision

37218 transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation

37236 transcatheter placement of an intravascular stent(s)(except lower extremity, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation

37237 transcatheter placement of an intravascular stent(s)(except lower extremity, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation

37238 transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein

37239 transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed, each additional vein

0075T transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiological supervision and interpretation, percutaneous; initial vessel

0076T transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiological supervision and interpretation, percutaneous; each additional vessel

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee. Carotid Stenting. Oct. 13, 2004.

Brott TG, Brown Jr. RD, Meyer FB, Miller DA, Cloft HJ, Sullivan TM. Carotid revascularization for prevention of stroke: carotid endarterectomy and carotid artery stenting. *Mayo Clin Proc.* Sept. 2004; 79(9):1197-1208.

ECRI, Target Database. Stents for Carotid Artery Stenosis. Accessed 4/8/04.

Winifred S. Hayes, Hayes Inc. Online. Carotid Artery Stenting for the Treatment of Carotid Artery Stenosis. March 2004.

Centers for Medicare and Medicaid Services. National Coverage Determination. Percutaneous Transluminal Angioplasty. Publication 100-3. Manual Section Number 20.7.

Yadav JS, Wholey MH, Kuntz RE, et. al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. *NEJM* Oct. 7, 2004; 351(15):1493-1501.

Hobson RW, Howard VJ, Roubin GS, et. al. Credentialing of surgeons and interventionalists for carotid artery stenting: experience from the lead-in phase of CREST. *J Vasc Surg.* Nov 2004;40(5):952-957.

Centers for Medicare and Medicaid Services. Decision Memo for Carotid Artery Stenting (CAG-00085R)

Creager MA, Winters WL, Hirshfeld JW, Lorell BH, Merli G, Rodgers GP, Tracy CM, White CJ. ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement on Vascular Medicine and Catheter-Based Peripheral Vascular Interventions. 2004 August 18;44(4):941-57.

SCAI/SVMB/SVS Writing Committee. Clinical competence statement on carotid stenting: Training and Credentialing for carotid stenting: Multi-specialty Consensus recommendations. *Catheterization and Cardiovascular Interventions* 2005;64:1-11.

Gurm HS, Yadav JS, Fayad P, et al. Long-term results of carotid stenting versus endarterectomy in high-risk patients. *J Engl J Med.* 2008 Apr 10; 358(15): 1572-9.

Brott TG, Halperin JL, Abbara S, et al. ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: executive summary. *Stroke.* Aug 2011;42(8):e420-463.

Spangler EL, Goodney PP, Schanzer A, et al. Outcomes of carotid endarterectomy versus stenting in comparable medical risk patients. *J Vasc Surg*. Nov 2014;60(5):1227-1231, 1231 e1221.

Paraskevas KI, Lazaridis C, Andrews CM, Veith FJ, Giannoukas AD. Comparison of cognitive function after carotid artery stenting versus carotid endarterectomy. *European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery*. Mar 2014;47(3):221-231.

Vincent S, Eberg M, Eisenberg MJ, Filion KB. Meta-analysis of randomized controlled trials comparing the long-term outcomes of carotid artery stenting versus endarterectomy. *Circulation. Cardiovascular quality and outcomes*. Oct 2015;8(6 Suppl 3):S99-108.

Li FM, Zhong JX, Jiang X, Wang QZ, Guo Y. Therapeutic effect of carotid artery stenting versus endarterectomy for patients with high-risk carotid stenosis. *International journal of clinical and experimental medicine*. 2014;7(9):2895-2900.

Kuliha M, Roubec M, Prochazka V, et al. Randomized clinical trial comparing neurological outcomes after carotid endarterectomy or stenting. *The British journal of surgery*. Feb 2015;102(3):194-201

Rosenfield K, Matsumura JS, Chaturvedi S, et al. Randomized trial of stent versus surgery for asymptomatic carotid stenosis. *N Engl J Med*. Mar 17 2016;374(11):1011-1020.

Spence JD, Naylor AR. Endarterectomy, stenting, or neither for asymptomatic carotid-artery stenosis. *N Engl J Med*. Mar 17 2016;374(11):1087-1088.

De Haro, J, Michel, I, Bleda, S, Canibano, C, Acin, F. Carotid Stenting in Patients With High Risk Versus Standard Risk for Open Carotid Endarterectomy (REAL-1 Trial). *The American journal of cardiology*. 2017 Jul 15;120(2):322-6.

Salzler GG, Farber A, Rybin DV, et al. The association of Carotid Revascularization Endarterectomy versus Stent Trial (CREST) and Centers for Medicare and Medicaid Services Carotid Guideline Publication on utilization and outcomes of carotid stenting among "high-risk" patients. *J Vasc Surg*. Jul 2017;66(1):104-111 e101.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/05

Revised: 3/05 (CMS expanded criteria); 3/06 (Provider Criteria expanded); 5/07; 2/11 (removal of PA). 4/17 (clarified criteria); 4/18 (add CMS criteria)

Reviewed: 5/08, 5/09, 5/10, 5/11, 5/12, 5/13, 5/14, 5/15, 5/16, 4/19, 4/20