

# Medical Coverage Policy



## Carotid Artery Stenting to Treat Carotid Artery Stenosis

Device/Equipment    Drug    Medical    Surgery    Test    Other

Effective Date:	12/1/2008	Policy Last Updated:	7/2/2013
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**Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

**Prospective review is not required.**

### Description:

Carotid artery angioplasty with stenting (CAS) is a treatment for carotid stenosis that is intended to prevent future stroke. It is an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy (CEA).

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (CEA). 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 an embolic protection device (EPD) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. Embolic protection devices can be deployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty rarely is performed without stent placement.

Proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local/regional anesthesia)
- Cranial nerve palsies are infrequent sequelae (although almost all following CEA resolve over time)
- Simultaneous procedures may be performed on the coronary and carotid arteries

The U.S. Food and Drug Administration (FDA) has approved carotid artery stents and EPDs from various manufacturers. Each FDA-approved carotid stent 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 greater than 50% stenosis, or asymptomatic with greater than 80% stenosis—degree of stenosis being assessed by ultrasound or angiogram with computed tomography (CT) angiography also sometimes used. Patients are considered at increased risk for complications during CEA if affected by any item from a list of anatomic features and comorbid conditions included in each stent system's Information for Prescribers.

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 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.

On April 30, 2007, a decision memo reaffirmed CMS's previous decision following a request to expand coverage while clarifying that "CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible." On October 14, 2008 in the sixth reconsideration, and on December 9, 2009 in the seventh reconsideration, CMS reaffirmed their prior coverage decisions.

A substantial body of Randomized Control Trial (RCT) evidence compares outcomes of carotid artery angioplasty with stenting (CAS) with carotid endarterectomy (CEA) for symptomatic and asymptomatic patients with carotid stenosis. The evidence does not support use of CAS in carotid artery disease for the average risk patient, since early adverse events are higher with CAS and long-term outcomes are not better. Data from RCTs and large database studies establish that the risks of CAS exceeds the threshold set to indicate overall benefit from the procedure. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS is considered not medically necessary.

However, based on limited data, clinical input, an indirect chain of evidence, and unmet medical need, CAS may be considered a reasonable treatment option in recently symptomatic patients when CEA cannot be performed due to anatomic reasons. For this population, CAS may be considered medically necessary. There is no scientific literature to support the use of CAS for all other indications, including carotid dissection, therefore all other indications are considered not medically necessary.

#### **Medical Criteria:**

##### **BlueCHiP for Medicare:**

Carotid Artery stenting procedures are considered medically necessary for one of the following conditions:

- I. Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis > 70%; **OR**
- II. Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%; **OR**
- III. Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis > 80%.\*

\*Patients 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), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7).

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and 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 ; and
- prior radiation treatment to the neck.

**Commercial:**

Carotid Artery stenting procedures are considered medically necessary for patients who meet all of the following conditions:

Carotid angioplasty with associated stenting and embolic protection may be considered medically necessary in patients with:

- 50–99% stenosis (NASCET measurement); AND
- symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days, symptom duration less than 24 hours, or nondisabling stroke; AND
- anatomic contraindication for carotid endarterectomy (such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).

**Policy:**

**Prior authorization is required for BlueCHIP for Medicare and recommended for all other lines of business.**

Carotid artery stenting to treat carotid artery stenosis is covered for when the above criteria is met, for all other indications Carotid artery stenting is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

**Coverage:**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, Benefit Booklet for applicable surgical coverage/benefits.

**Coding:****All Products:**

The following codes are **medically necessary** when the above medical criteria is met:  
**37215**

The following codes are **not medically necessary**:  
**37216 0075T 0076T**

**Also known as:**

None

**Related topics:**

None

**Published:**

Provider Update, September 2013  
Provider Update, December 2012  
Provider Update, May 2011  
Provider Update, June 2010  
Provider Update, June 2009  
Provider Update, September 2008  
Provider Update, October 2007  
Provider Update, June 2006

**References:**

<sup>1</sup> CMS. Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting. January 5, 2007;Transmittal 64:Change Request 5432.

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BlueCross BlueShield Association Tec Assessment Program. Angioplasty and Stenting of the Cervical Carotid Artery with Distal Embolic Protection of the Cerebral Circulation. June 2007;22:1

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**History:**

Annual Review - May 2013

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