I. Description

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 open carotid endarterectomy (CEA) currently considered the standard treatment for patients 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. 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.

Proposed advantages of CAS over CEA include:

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

II. Criteria/Guidelines

Carotid angioplasty with associated stenting and embolic protection is covered (subject to Limitations/Exclusions and Administrative Guidelines) for patients with:

A. 50% - 99% stenosis (NASCET measurement); AND
B. 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
C. Anatomic contraindication for carotid endarterectomy (such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy)

III. Limitations/Exclusions

Carotid angioplasty with or without associated stenting and embolic protection is not covered for all other indications.

IV. Administrative Guidelines

A. Precertification is not required.
B. The following documentation must be kept in the patient's medical records and be made available to HMSA upon request:
   1. Clinical notes documenting the patient's symptoms of carotid artery stenosis and any high risk conditions for CEA.
   2. Imaging studies documenting the degree of carotid stenosis as measured by a duplex Doppler ultrasound or carotid artery angiography.

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<th>Description</th>
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<tr>
<td>37215</td>
<td>Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous, with distal embolic protection</td>
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<th>CPT Codes</th>
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<td>0075T</td>
<td>Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel</td>
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<tr>
<td>0076T</td>
<td>each additional vessel</td>
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V. Rationale

Results were available from 18 multicenter prospective registries collectively enrolling 20,194 patients arguably the most generalizable and applicable evidence available for outcomes following CAS. Eleven registries enrolled patients in accordance with FDA labeling and 30-day outcomes were available according to symptomatic status (13,783 asymptomatic and 3,353 symptomatic). In 9 registries, 30-day death/stroke rates were either reported or obtained from investigators; in the remaining 2 death/stroke rates were estimated from 30-day death/stroke/MI and MI rates. For asymptomatic patients, the pooled periprocedural death/stroke rate was 3.9% (95% CI: 3.3–4.4); for symptomatic patients 7.4% (95% CI: 6.0–9.0). Combined data from 2 registries reported
acceptable periprocedural death/stroke rates for patients with unfavorable anatomy but included only 371 asymptomatic and 60 symptomatic patients. No other registry reported results by symptomatic status for those subgroups.

Long-term follow-up of SAPPHIRE (3-year), SPACE (2-year), and EVA-3S (4-year) were reported. Approximate annual ipsilateral stroke rates from day 31 through longest follow-up for CAS and CEA, respectively, were in SPACE 0.4% and 0.4% and in EVA-3S 1.1% and 0.9%. These results support a conclusion that following the periprocedural period (i.e., 31 days to longest follow-up) stroke risk reduction in symptomatic patients not selected for medical or anatomic comorbidities is similar with either CAS or CEA. In SAPPHIRE for asymptomatic and symptomatic patients combined, ipsilateral strokes from day 31 to 1,080 days were observed in 4.4% of patients undergoing CAS and 3.6% with CEA (from digitized figure). In SPACE, recurrent stenosis >70% was more frequent 2 years following CAS (10.7% vs. 4.6%). Two-year restenosis rates >50% reported to the FDA in SAPPHIRE were 17.3% following CAS and 13.3% after CEA (studies obtained in 75 patients undergoing CAS in 45 CEA cases).

Numerous meta-analyses have pooled comparative periprocedural death/stroke rates in CEA and CAS. Despite differences in methods, all consistently found similar relative increases in 30-day death/stroke risk following CAS as compared to CEA. The most current Cochrane Review concludes, “overall, the data are insufficient to support a change from routine clinical practice in the types of patient for which carotid endarterectomy is the current standard treatment.”

Summary

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 in recently symptomatic patients when CEA cannot be performed due to anatomic reasons.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government
approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA consider the application of this Medical Policy to the case at issue.

VII. References


