

**Health Technology Clinical Committee  
Findings and Decision**

**Topic:** Carotid Artery Stenting  
**Meeting Date:** September 20, 2013  
**Final Adoption:** November 15, 2013

**Meeting materials and transcript are available on the HTA website at:**  
<http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx>

**Number and Coverage Topic:**

20130920B – Carotid Artery Stenting

**HTCC Coverage Determination:**

Carotid Artery Stenting is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

**HTCC Reimbursement Determination:**

**Limitations of Coverage:**

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high surgical risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high surgical risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

**Non-Covered Indicators**

Carotid Artery Stenting of intracranial arteries is **not covered**.

**Definition of high risk includes:**

Patients at high surgical 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. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;

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- 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.

**Definition of symptoms of carotid artery stenosis include:** carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale  $\geq$  3) shall be excluded from coverage.

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

## HTCC Coverage Vote and Formal Action

### *Committee Decision*

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on Carotid Artery Stenting demonstrates that there is sufficient evidence to cover with conditions. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions Carotid Artery Stenting.

### Carotid Artery Stenting

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Carotid Artery Stenting	0	0	11

### *Discussion*

The Chair called for discussion of conditions of coverage for Carotid Artery Stenting following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

#### Limitations of Coverage:

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high surgical risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high surgical risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

#### Non-Covered Indicators

Carotid Artery Stenting of intracranial arteries is **not covered**.

#### Definition of high risk includes:

Patients at high surgical 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. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 %;
- Unstable angina;

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- 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.

**Definition of symptoms of carotid artery stenosis include:** carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale  $\geq$  3) shall be excluded from coverage.

### **Action**

The committee checked for availability of a Medicare coverage decision. There is a national coverage determination (NCD) for Carotid Artery Stenting (CAS). The committee reviewed the NCD and determined that based the availability of more recent study evidence to: cover symptomatic extracranial CAS without a requirement of study participation for patient at high surgical risk for CEA with stenosis of 50% or greater; to cover without a requirement of study participation for asymptomatic patients at high risk of surgery for CEA with  $\geq$ 80% stenosis. These criteria provide access to coverage similar to the NCD without study participation as a requirement.

The committee determined noncoverage for intracranial stents based on evidence indicating serious safety concerns, and recognizing that state agency programs may provide coverage in the context of research.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Carotid Artery Stenting reflective of the majority vote for final approval at the next public meeting.

### **Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply

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### **Final**

with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.