Extracranial Carotid Artery Stenting

Description

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

OBJECTIVE

The objective of this evidence review is to determine whether the use of extracranial carotid artery stenting improves the net health outcome in patients with carotid artery stenosis.

POLICY STATEMENT

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

- 50% to 99% stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] measurement); AND
- symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in the previous 120 days, symptom duration less than 24 hours, or nondisabling stroke; AND
- anatomic contraindication for carotid endarterectomy (eg, prior radiotherapy or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).
Carotid angioplasty with associated stenting and embolic protection is considered **not medically necessary** for all other indications, including but not limited to, patients with carotid stenosis who are suitable candidates for carotid endarterectomy and patients with carotid artery dissection.

Carotid angioplasty without associated stenting and embolic protection is considered **not medically necessary** for all indications, including but not limited to, patients with carotid stenosis who are suitable candidates for carotid endarterectomy and patients with carotid artery dissection.

**POLICY GUIDELINES**

The intent of the second investigational policy statement is that carotid angioplasty with embolic protection but without stenting is investigational. There may be unique situations where the original intent of surgery was to perform carotid angioplasty with stenting and embolic protection, but anatomic or other considerations prohibited placement of the stent.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**FDA REGULATORY STATUS**

A number of CAS and EPDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) or the 510(k) process. Table 1 lists the original PMA’s with product code NIM and Table 2 lists 510(k) approvals with product code NTE.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Device</th>
<th>PMA</th>
<th>PMA Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cordis Corp.</td>
<td>Cordis Precise Nitinol Stent System</td>
<td>P030047</td>
<td>Sept 2006</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Acculink Carotid Stent System and Rx Acculink Carotid Stent System</td>
<td>P040012</td>
<td>Aug 2004</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>XACT Carotid Stent System</td>
<td>P040038</td>
<td>Sep 2005</td>
</tr>
<tr>
<td>Boston Scientific Corp.</td>
<td>Carotid Wallstent Monorail Endoprosthesis</td>
<td>P050019</td>
<td>Oct 2005</td>
</tr>
<tr>
<td>Boston Scientific Corp.</td>
<td>Endotex Nexstent Carotid Stent and Delivery System and Endotex Carotid Stent and Monorail Delivery System</td>
<td>P050025</td>
<td>Oct 2006</td>
</tr>
<tr>
<td>Medtronic Vascular</td>
<td>iProtege GPS and Protege Rx Carotid Stent Systems</td>
<td>P060001</td>
<td>Jan 2007</td>
</tr>
<tr>
<td>Silk Road Medical, Inc.</td>
<td>Enroute Transcarotid Stent System</td>
<td>P140026</td>
<td>May 2015</td>
</tr>
<tr>
<td>W. L Gore &amp; Associates, Inc</td>
<td>Gore Carotid Stent</td>
<td>P180010</td>
<td>Nov 2018</td>
</tr>
</tbody>
</table>

PMA: Premarket approval

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Table 2. FDA 510(k) Carotid Artery Stents and Embolic Protection Devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Stents and Devices</th>
<th>510(k) Number</th>
<th>PMA/510(k) Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidant, now Abbott Vascular</td>
<td>Accunet and RX Accunet Embolic protection system</td>
<td>K042218</td>
<td>Aug 2004</td>
</tr>
<tr>
<td>Guidant, now Abbott Vascular</td>
<td>Rx Accunet 2 Embolic Protection System</td>
<td>K042908</td>
<td>Nov 2004</td>
</tr>
<tr>
<td>Guidant, now Abbott Vascular</td>
<td>Rx Accunet Embolic Protection System</td>
<td>K052165</td>
<td>Aug 2005</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Emboshield embolic protection system</td>
<td>K052454</td>
<td>Sep 2005</td>
</tr>
<tr>
<td>Cordis Corp.</td>
<td>AngioGuard XP and RX emboli capture guidewire systems</td>
<td>K062531</td>
<td>Sep 2006</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>FilterWire EZ™ embolic protection system</td>
<td>K063313</td>
<td>Dec 2006</td>
</tr>
<tr>
<td>EV3 Inc</td>
<td>Spiderx</td>
<td>K052659</td>
<td>Feb 2007</td>
</tr>
<tr>
<td>EV3 Inc</td>
<td>Spidefx</td>
<td>K063204</td>
<td>Nov 2007</td>
</tr>
<tr>
<td>GORE</td>
<td>GORE Flow Reversal System</td>
<td>K083300</td>
<td>Feb 2009</td>
</tr>
<tr>
<td>GORE</td>
<td>GORE Embolic Filter</td>
<td>K103500</td>
<td>May 2011</td>
</tr>
<tr>
<td>Medtronic/Invatec</td>
<td>Mo.Ma Ultra Proximal Cerebral Protection Device</td>
<td>K092177</td>
<td>Oct 2009</td>
</tr>
<tr>
<td>Silk Road Medical</td>
<td>ENROUTE™ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System</td>
<td>K143072</td>
<td>Feb 2015</td>
</tr>
<tr>
<td>Gardia Medical</td>
<td>Wirion</td>
<td>K143570</td>
<td>Jun 2015</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Rx Accunet Embolic Protection System</td>
<td>K153086</td>
<td>Nov 2015</td>
</tr>
<tr>
<td>Silk Road Medical, Inc.</td>
<td>Enroute Transcarotid Neuroprotection System</td>
<td>K153485</td>
<td>Mar 2016</td>
</tr>
<tr>
<td>Gardia Medical Ltd.</td>
<td>Wirion</td>
<td>K180023</td>
<td>Mar 2018</td>
</tr>
<tr>
<td>Contego Medical, LLC</td>
<td>Paladin Carotid Post-Dilation Balloon System With Integrated Embolic Protection (Paladin System)</td>
<td>K181128</td>
<td>Sep 2018</td>
</tr>
<tr>
<td>Contego Medical, LLC</td>
<td>Vanguard lep Peripheral Balloon Angioplasty System With Integrated Embolic Protection</td>
<td>K181529</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>Abbott Vascular</td>
<td>Emboshield Nav6 Embolic Protection System, Barewire Filter Delivery Wires</td>
<td>K191173</td>
<td>Jul 2019</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration; PMA: premarket approval.

Each FDA-approved carotid stent is indicated for combined use with an EPD to reduce risk of stroke in patients considered at increased risk for periprocedural complications from CEA who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis with degree of stenosis assessed by ultrasound or angiogram, with computed tomography angiography also 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.

The RX Acculink Carotid Stent System is also approved for use in conventional risk patients (not considered at increased risk for complications during CEA) with symptoms and 70% or more stenosis by ultrasound or 50% or more stenosis by angiogram, and asymptomatic patients with 70% or more stenosis by ultrasound or 60% or more stenosis by angiogram.

The FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the rapid exchange devices designed for more rapid stent and filter expansion. The FDA has mandated postmarketing studies for EPDs, 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 (eg, straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

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In 2015, the ENROUTE™ Transcarotid Neuroprotection System was cleared for marketing by the FDA through the 510(k) process. ENROUTE™ is a flow reversal device designed to be placed via direct carotid access.

FDA product codes: NIM (stents) and NTE (EPDs).

**RATIONALITY**

**Summary of Evidence**

For individuals who have carotid artery stenosis who receive carotid artery stenting (CAS), the evidence includes randomized controlled trials and systematic reviews of these trials. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. A substantial body of randomized controlled trial evidence has compared outcomes of CAS with CEA for symptomatic and asymptomatic patients with carotid stenosis. The evidence does not support the use of CAS in carotid artery disease for the average-risk patient because early adverse events are higher with CAS and long-term outcomes are similar between the two procedures. Data from randomized controlled trials and large database studies have established that the risk of death or stroke with CAS exceeds the threshold considered acceptable to indicate overall benefit from the procedure. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS does not improve health outcomes. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**American Stroke Association**

The American Stroke Association (2011), with 13 other medical societies, issued guidelines on the management of extracranial carotid and vertebral artery diseases, which are summarized in Table 3. [67, 68, 69].

**Table 3. Guidelines for Managing Patients With Extracranial Carotid and Vertebral Artery Disease**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS is indicated as an alternative to CEA for symptomatic patients at average or low-risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by &gt;70%, as documented by noninvasive imaging or &gt;50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is &lt;6% (360)</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>Selection of asymptomatic patients for carotid revascularization should be guided by an assessment of comorbid conditions, life expectancy, and other individual factors and should include a thorough discussion of the risks and benefits of the procedure with an understanding of patient preferences</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>It is reasonable to choose CEA over CAS when revascularization is indicated in older patients, particularly when arterial pathoanatomy is unfavorable for endovascular intervention</td>
<td>Iia</td>
<td>B</td>
</tr>
<tr>
<td>It is reasonable to choose CAS over CEA when revascularization is indicated in patients with neck anatomy unfavorable for arterial surgery</td>
<td>Iia</td>
<td>B</td>
</tr>
<tr>
<td>When revascularization is indicated for patients with TIA or stroke and there are no contraindications to early revascularization, intervention within 2 wk of the index event is reasonable rather than delaying surgery</td>
<td>Iia</td>
<td>B</td>
</tr>
</tbody>
</table>

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Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established

In symptomatic or asymptomatic patients at high-risk of complications for carotid revascularization by either CEA or CAS because of comorbidities, the effectiveness of revascularization versus medical therapy alone is not well established

Carotid angioplasty and stenting might be considered when ischemic neurologic symptoms have not responded to antithrombotic therapy after acute carotid dissection

Except in extraordinary circumstances, carotid revascularization by either CEA or CAS is not recommended when atherosclerosis narrows the lumen by <50%

Carotid revascularization is not recommended for patients with chronic total occlusion of the targeted carotid artery

Carotid revascularization is not recommended for patients with severe disability caused by cerebral infarction that precludes preservation of useful function

CAS: carotid artery angioplasty with stenting; CEA: carotid endarterectomy; COR: class of recommendation; LOE: level of evidence; TIA: transient ischemic attack.

a Class I: benefit >>> risk; class IIa benefit >> risk; class IIb benefit ≥ risk; class III: no benefit.

b Level A (data derived from multiple randomized controlled trials or meta-analyses; multiple populations evaluated); level B (data derived from a single randomized controlled trial or nonrandomized studies; limited populations evaluated); level C (only consensus opinion of experts, case studies, or standard of care; very limited populations evaluated).

Society for Vascular Surgery

The Society for Vascular Surgery (2011) updated its guidelines on the management of the extracranial carotid disease. Recommendations from the guidelines are summarized in Table 4.

Table 4. Guidelines for Managing Extracranial Carotid Disease

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GOEa</th>
<th>LOEb</th>
</tr>
</thead>
<tbody>
<tr>
<td>In most patients with carotid stenosis who are candidates for intervention, CEA is preferred to CAS for reduction of all-cause and periprocedural death</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>CAS is preferred over CEA in symptomatic patients with &gt;50% stenosis and tracheal stoma, situations where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy, prior cranial nerve injury, and lesions that extend proximal to the clavicle or distal to the C2 vertebral body</td>
<td>II</td>
<td>B</td>
</tr>
<tr>
<td>CAS is preferred over CEA in symptomatic patients with &gt;50% stenosis and severe uncorrectable coronary artery disease, congestive heart failure, or chronic obstructive pulmonary disease</td>
<td>II</td>
<td>C</td>
</tr>
<tr>
<td>There are insufficient data to recommend CAS as primary therapy for neurologically asymptomatic patients with 70%-99% diameter stenosis. In properly selected asymptomatic patients, CAS is equivalent to CEA in the hands of experienced interventionalists with a combined stroke and death rate &lt;3%</td>
<td>II</td>
<td>B</td>
</tr>
</tbody>
</table>

CAS: carotid artery angioplasty with stenting; CEA: carotid endarterectomy; GOE: grade of evidence; LOE: level of evidence.

a Grade I: benefit clearly outweighs risk; grade II: benefits and risks are more closely matched and are more dependent on specific clinical scenarios.

b Level B (moderate quality); level C (low quality).

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

The Center for Medicaid & Medicare Services (CMS; 2001) issued national coverage policy that restricted coverage for carotid angioplasty and stenting to patients participating in a clinical trial with category B investigational device exemption (IDE) designation from the U.S. Food and Drug Administration (FDA). Percutaneous transluminal angioplasty of the vertebral and cerebral arteries remained noncovered.

When the FDA approved the first (Guidant) devices, Medicare coverage under the IDE was no longer available for that manufacturer’s devices and was not applicable to the FDA-required postapproval studies. Thus, in 2004, Medicare broadened its national coverage policy and “determined that the evidence is adequate to conclude that percutaneous transluminal angioplasty with carotid stent placement is reasonable and necessary when performed consistent with the FDA approval of the carotid stent device and in an FDA required post-approval study.” For unapproved stents and embolic protection devices, the prior policy remained in effect and restricted coverage to patients participating in an FDA-approved category B IDE trial of stent placement in the cervical carotid artery.

While the Medicare decision differed from the conclusions of this evidence review, Medicare made a public policy decision "that making available new, effective therapies aimed at addressing treatment and prevention of cerebrovascular disease was important to Medicare beneficiaries." Medicare also noted that it recognized the value in supporting postapproval studies as "the collected data may provide an opportunity for practitioners to determine which patients are most appropriate for carotid artery stenting and to reinforce IDE trial data on health outcomes and adverse events."

CMS provides a continually updated listing of facilities eligible for Medicare reimbursement that meet CMS’s minimum facility standards for performing CAS for high-risk patients.

In 2005, CMS determined that CAS with embolic protection devices was reasonable and necessary for patients at high-risk for carotid endarterectomy (CEA) who also have symptomatic carotid artery stenosis 70% or more. CMS limited coverage for these patients to procedures performed using the FDA-approved devices. CMS also limited coverage for patients at high-risk for CEA with symptomatic carotid artery stenosis between 50% and 70%, and for patients at high-risk for CEA with asymptomatic stenosis 80% or more, to the FDA-approved category B IDE clinical trials for unapproved devices, or to the FDA-required postapproval studies for approved devices. CMA defined patients at high-risk for CEA as having significant comorbidities and/or anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection) who would be poor candidates for CEA in the opinion of a surgeon.

In 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." In 2008, in a sixth reconsideration, and in 2009, in a seventh reconsideration, CMS reaffirmed its prior coverage decisions.

In 2012, CMS convened a Medicare Evidence Development & Coverage Advisory Committee panel to consider management of carotid atherosclerosis. Medicare Evidence Development & Coverage Advisory Committee panel members voted on specific questions using a scale of 1 (low confidence) to 5 (high confidence). For symptomatic patients not considered at high-risk, the mean scores to the question of whether CAS is the favored treatment strategy in this population was 1.85 and for CEA 3.6. For asymptomatic patients not considered high-risk, the evidence was judged to have not reached a level of certainty to determine a favored treatment.

REFERENCES


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### POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2012</td>
<td>New policy</td>
<td>Policy updated with literature review; References added, renumbered, and some removed. Carotid dissection added to policy as investigational, clarified policy statement to read that CAS is investigational for those who are suitable candidates for CEA.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Replace policy</td>
<td>Policy update with literature review adding references 24, 28-29, 35-37, 49-50 and 53. Policy statement is unchanged.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review adding references 24, 28-29, 35-37, 49-50 and 53. Policy statement is unchanged.</td>
</tr>
<tr>
<td>September 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 30, 34, 38-39, and 54 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 5, 2018; references 52, 60, 69, 73, and 75 added. Investigational policy statements separated for carotid angioplasty with or without associated stenting. Policy statements otherwise unchanged.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with review of literature through March 20, 2019; international guidelines removed, 2019 PMA information added; no references added. Policy statements unchanged except &quot;investigational&quot; changed to &quot;not medically necessary&quot; due to FDA PMA status.</td>
</tr>
<tr>
<td>September 2020</td>
<td>Replace policy</td>
<td>Policy updated with review of literature through March 13, 2020; references added. Policy statements unchanged.</td>
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