The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Carotid artery angioplasty with stenting 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.

Background

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. The procedure is most often performed through the femoral artery, but a transcervical approach can also be used to avoid traversing the aortic arch. The procedure typically takes 20 to 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. Examples include:

- Acculink™ and RX Acculink™ carotid stents and Accunet™ and RX Accunet™ cerebral protection filters, Guidant Corp. (approved August 2004);
- Xact® RX carotid stent system and Emboshield® embolic protection system, Abbott Vascular Devices (approved September 2005);
- Precise® nitinol carotid stent system and AngioGuard™ XP and RX emboli capture guidewire systems, Cordis Corp. (approved September 2006);
- NexStent® carotid stent over-the-wire and monorail delivery systems, Endotex Interventional Systems; and FilterWire EZ™ embolic protection system, Boston Scientific Corp. (approved October 2006);
- ProtégéRx® and SpideRx®, ev3 Inc., Arterial Evolution Technology (approved January 2007);
- Carotid Wallstent®, Boston Scientific Corp. (approved October 2008);
- GORE® Flow Reversal System (clearance February 2009); GORE® Embolic Filter (clearance May 2011)
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- Mo.Ma® Ultra Proximal Cerebral Protection Device, Invatec SPA (clearance October 2009).

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.

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% stenosis by ultrasound or ≥ 50% stenosis by angiogram, and asymptomatic patients with ≥ 70% stenosis by ultrasound or ≥ 60% stenosis by angiogram.

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 Precise® and AngioGuard™ devices were studied in a randomized controlled trial (the SAPPHIRE trial). Other devices were approved based on uncontrolled, single-arm trials or registries and comparison to historical controls. 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.

Policy (Formerly Corporate Medical Guideline)

Carotid angioplasty with associated stenting and embolic protection may be considered medically necessary in patients with:
- 50–99% stenosis (North American Symptomatic Carotid Endarterectomy Trial [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).

Carotid angioplasty with or without associated stenting and embolic protection is considered investigational for all other indications, including but not limited to, patients with carotid stenosis who are suitable candidates for CEA and patients with carotid artery dissection.

Medicare Advantage

For Medicare Advantage, PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection is considered medically necessary for members who are at high risk for CEA and who also have symptomatic carotid artery stenosis ≥ 70%. This is limited to procedures performed using FDA-approved carotid artery stenting systems and FDA-approved or -cleared embolic protection devices. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is investigational.

For Medicare Advantage PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection is also considered medically necessary related to these Food and Drug Administration (FDA)-approved Category B Investigational Device Exemption (IDE) Clinical Trials:
- Members who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost of clinical
trials, or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual 20.7);

- Members who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥ 80%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost of clinical trials, or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7).

Coverage is limited to procedures performed using FDA-approved carotid artery stents and FDA-approved or -cleared embolic protection devices. If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is considered investigational.

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. 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.

Symptoms of carotid artery stenosis include carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a nondisabling stroke (modified Rankin scale less than three with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ three) shall be excluded from coverage.

In addition, CAS with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes.

CAS with embolic protection is reasonable and necessary only if performed in Medicare approved facilities found at [http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp](http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp).

All indications for PTA with or without stenting to treat obstructive lesions of the vertebral arteries remain investigational. Refer to Protocol Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) for cerebral arteries. All other indications for PTA without stenting are investigational.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced
procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


57. Centers for Medicare and Medicaid Services National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7), Implementation Date 3/11/2013 for services after 01/01/2013.