

Protocol

Extracranial Carotid Artery Stenting

(70168)

Medical Benefit		Effective Date: 10/01/12	Next Review Date: 05/21
Preauthorization	No	Review Dates: 01/08, 09/08, 09/09, 09/10, 09/11, 07/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With carotid artery stenosis	Interventions of interest are: <ul style="list-style-type: none">• Carotid artery stenting	Comparators of interest are: <ul style="list-style-type: none">• Carotid endarterectomy	Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Morbid events• Treatment-related mortality• Treatment-related morbidity

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).

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. The 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.

Based on limited data, clinical input, a 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. It is considered investigational for all other indications, including carotid artery dissection.

POLICY

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 the previous 120 days, symptom duration less than 24 hours, or nondisabling stroke; AND
- anatomic contraindication for carotid endarterectomy (e.g., prior radiotherapy or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).

Carotid angioplasty with 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 carotid endarterectomy and patients with carotid artery dissection.

Carotid angioplasty without associated stenting and embolic protection is considered **investigational** 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.

MEDICARE ADVANTAGE

For all indications coverage is limited to procedures performed using FDA-approved carotid artery stents and FDA-approved or -cleared embolic protection devices.

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 (see Medicare Advantage Policy Guidelines).

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 the following:

- patients who are at high risk for CEA (see Medicare Advantage Policy Guidelines) and
- who also have symptomatic carotid artery stenosis greater than or equal to 70%.

All indications for PTA with or without stenting to treat obstructive lesions of the vertebral arteries remain **investigational**.

If deployment of the embolic protection device is not technically possible, and not performed, then the procedure is considered **investigational**.

All other indications for PTA without stenting are **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*:

- Patients 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);
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis greater than or equal to 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).

MEDICARE ADVANTAGE POLICY GUIDELINES

Refer to the Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) Protocol for policy on cerebral arteries.

CAS with embolic protection is reasonable and necessary only if performed in Medicare approved facilities found at <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-Facilities.html>.

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) less than 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, SAPPHERE, 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 greater than or equal to three) shall be excluded from coverage.

BACKGROUND

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to carotid endarterectomy (CEA). Carotid artery 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) to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. EPDs can be de-

ployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty is rarely performed without stent placement.

The proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local or 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.

REGULATORY STATUS

A number of CAS and EPDs have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval or the 510(k) process. Examples are provided in Table 1.

Table 1. FDA-Approved Carotid Artery Stents and Embolic Protection Devices

Manufacturer	Stents and Devices	PMA/510(k) Date
Guidant, now Abbott Vascular	Acculink™ and RX Acculink™ carotid stents	Aug 2004
Guidant, now Abbott Vascular	Accunet™ and RX Accunet™ cerebral protection filters	Aug 2004
Abbott Vascular	Xact® RX carotid stent system	Sep 2005
Abbott Vascular	Emboshield® embolic protection system	Sep 2005
Cordis Corp.	Precise® nitinol carotid stent system	Sep 2006
Cordis Corp.	AngioGuard™ XP and RX emboli capture guidewire systems	Sep 2006
EndoTex Interventional Systems	NexStent® carotid stent over-the-wire and monorail delivery systems	Oct 2006
Boston Scientific	FilterWire EZ™ embolic protection system	Oct 2006
ev3, Arterial Evolution Technology	Protégé® Rx and SpideRx®	Jan 2007
Boston Scientific	Carotid Wallstent®	Oct 2008
GORE	GORE® Flow Reversal System	Feb 2009
GORE	GORE® Embolic Filter	May 2011
Medtronic/Invatec	Mo.Ma® Ultra Proximal Cerebral Protection Device	Oct 2009
Silk Road Medical	ENROUTE™ Transcarotid Stent System and ENROUTE Transcarotid Neuroprotection System	May 2015

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 (e.g., straight or tapered) and sizes (diameters and lengths) to match the vessel lumen that will receive the stent.

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).

RELATED PROTOCOLS

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Endovascular Therapies for Extracranial Vertebral Artery Disease

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

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