Protocol

Extracranial Carotid Artery Stenting

(70168)

Medical Benefit		**Effective Date**: 10/01/12	**Next Review Date**: 05/23
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, 05/21, 05/22	

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.

RELATED PROTOCOLS

Endovascular Procedures for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Endovascular Therapies for Extracranial Vertebral Artery Disease

Populations	Interventions	Comparators	Outcomes
Individuals: • With carotid artery stenosis	Interventions of interest are: • Carotid artery stenting	Comparators of interest are: • Carotid endarterectomy	Relevant outcomes include: • 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. 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 2 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 out-

comes. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

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, 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 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. Embolic protection devices can be deployed 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 (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 1. FDA Premarket Approvals for Carotid Artery Stents and Embolic Protection Devices

Manufacturer	Device	PMA	PMA Date
Cordis Corp.	Cordis Precise Nitinol Stent System	P030047	Sept 2006
Abbott Vascular	Acculink Carotid Stent System and Rx Acculink Carotid Stent System	P040012	Aug 2004
Abbott Vascular	XACT Carotid Stent System	P040038	Sep 2005
Boston Scientific Corp.	Carotid Wallstent Monorail Endoprosthesis	P050019	Oct 2008
Boston Scientific Corp.	Endotex Nexstent Carotid Stent and Delivery System and Endotex Carotid Stent and Monorail Delivery System	P050025	Oct 2006
Medtronic Vascular	jProtege GPS and Protege Rx Carotid Stent Systems	P060001	Jan 2007
Medtronic Vascular	Exponent Self-Expanding Carotid Stent System with Over-the-Wire or Rapid-Exchange Delivery System	P070012	Oct 2007
Silk Road Medical, Inc.	Enroute Transcarotid Stent System	P140026	May 2015
W. L Gore & Associates, Inc Gore Carotid Stent	Gore Carotid Stent	P180010	Nov 2018

PMA: Premarket approval

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

Manufacturer	Stents and Devices	510(k) Number	PMA/ 510(k) Date
Guidant, now Abbott Vascular	Accunet and RX AccunetEmbolic protection system	K042218	Aug 2004
Guidant, now Abbott Vascular	Rx Accunet 2 Embolic Protection System	K042908	Nov 2004
Guidant, now Abbott Vascular	Rx Accunet Embolic Protection System	K052165	Aug 2005
Abbott Vascular	Emboshield® embolic protection system	K052454	Sep 2005

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

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 Acculinka 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 post marketing 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).

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.**

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

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