MEDICAL POLICY

POLICY TITLE	EXTRACRANIAL CAROTID ANGIOPLASTY/STENTING
POLICY NUMBER	MP-2.008

Original Issue Date (Created):	**7/1/2002**
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Effective Date:	**8/1/2018**

I. POLICY

TOP

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 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 (CEA) and patients with carotid artery dissection. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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.

II. PRODUCT VARIATIONS TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.68, Extracranial Carotid Angioplasty/Stenting. The FEP Medical Policy manual can be found at: www.fepblue.org.

III. DESCRIPTION/BACKGROUND TOP

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) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. EPDs can be deployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty rarely is performed without stent placement.

The 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.

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. Examples are provided in Table 1.

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

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

Manufacturer	Stents and Devices	PMA/510K 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 Inc., 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 to be at increased risk for periprocedural complications from carotid endarterectomy (CEA) who are symptomatic with greater than 50% stenosis, or asymptomatic with greater than 80% stenosis degree of stenosis assessed by ultrasound or angiogram with computed tomography 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 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.

FDA-approved stents and EPDs differ in the deployment methods used once they reach the target lesion, with the rapid exchange (RX) devices designed for more rapid stent and filter expansion. The Precise® and AngioGuard were studied in a randomized controlled trial (SAPPHIRE; see Rationale section). 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 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 February 2015, the Enroute Transcarotid NPS (Silk Road Medical, Sunnyvale, CA) was cleared for marketing by FDA through the 510(k) process. The Enroute is a flow-reversal device designed to be placed via direct carotid access. Clearance was based on results of the Roadster trial (NCT01685567), a single-arm phase 3 pivotal trial to evaluate outcomes after CAS with the Enroute device among 283 subjects with symptomatic or asymptomatic carotid stenosis.

IV. RATIONALE

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Summary of Evidence

For individuals who have carotid artery stenosis who receive 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 RCT 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 RCTs 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.

V. DEFINITIONS

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ANGIOPLASTY is an endovascular procedure that reopens narrowed blood vessels and restores forward blood flow.

STENT is a material or device used to hold tissue in place, to maintain open blood vessels, or to provide a support for a graft or anastomosis while healing is taking place.

CAROTID ARTERY pertains to the right and left common carotid arteries, which form the principal supply to the head and neck.

CAROTID ENDARTERECTOMY is a surgical technique for removing intra-arterial obstructions of the proximal cervical portion of the internal carotid artery. The technique reduces the risk of stroke when it is performed on a patient with moderate or severe stenosis of the artery, with or without a history of transient ischemic attacks.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and

providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes ®							
37215	37216	37217	37218	37236	37237		

ICD-10-CM Diagnosis Code*	Description
I63.231	Cerebral infarction due to unspecified occlusion or stenosis of right carotid arteries
I63.232	Cerebral infarction due to unspecified occlusion or stenosis of left carotid arteries
I65.21	Occlusion and stenosis of right carotid artery
I65.22	Occlusion and stenosis of left carotid artery
I65.23	Occlusion and stenosis of bilateral carotid arteries

IX. REFERENCES

TOP

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With the American Academy of Neurology and Society of Cardiovascular Computed Tomography. J Am Coll Cardiol. Feb 22 2011;57(8):e16-94. PMID 21288679

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X. POLICY HISTORY

TOP

MP-2.008	**CAC 2/25/03**
	CAC 12/14/04
	CAC 1/31/06
	CAC 1/30/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 9/29/09 Consensus Review
	CAC 5/25/10 Minor review. Guidelines revised, however no change to coverage. Intracranial percutaneous stenting criteria removed from policy and policy retitled, "Extracranial Angioplasty/Stenting." FEP PPO variation added to the policy.
	CAC 7/26/11 Consensus Review
	CAC 6/26/12 Adopt BCBSA. Carotid dissection added to policy statement as investigational, and policy statement clarified to read that CAS is investigational in patients who are suitable candidates for CEA. Changed FEP variation to reference the FEP Medical Policy Manual MP-7.01.68 External Carotid Angioplasty/Stenting
	Admin Review Complete 7.16.13
	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements. Rationale added.
	12/19/2013- New 2014 Code updates made.
	CAC 7/22/14 Consensus. No change to policy statements. References updated.
	CAC 7/21/15 Consensus review. No changes to the policy statements, Background, rationale, and references updated. Codes reviewed.
	CAC 7/25/16 Consensus. No change to policy statements. Background, rationale and references updated. Coding updated**.**
	Admin update 1/1/17: Product variation section reformatted.
	CAC 9/26/17 Consensus review. Policy statements separated for carotid angioplasty with or without stenting. Policy statements otherwise unchanged. Background, rationale, and references updated**.** Coding reviewed.

POLICY TITLE	EXTRACRANIAL CAROTID ANGIOPLASTY/STENTING
POLICY NUMBER	MP-2.008

	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	6/04/18 Consensus review. Policy statements unchanged. FEP policy title updated. Description/Background, Rationale and Reference sections updated.

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