



BlueCross BlueShield
of Alabama

Name of Policy:

Extracranial Carotid Angioplasty/Stenting

Policy #: 221
Category: Surgery

Latest Review Date: May 2008
Policy Grade: A

Background:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Description of Procedure or Service:

Carotid angioplasty with or without associated stenting has been investigated as a less invasive alternative to open carotid endarterectomy (CEA), currently considered the standard treatment for patients with significantly stenosing carotid atherosclerosis. Note that either alternative is added to optimal medical management for these patients. Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices through the femoral artery and into the carotid artery. The procedure is performed with the patient fully awake and without sedation. At present, most practitioners also use a distally placed embolic protection (DEP) device that is designed to reduce the risk of peri-procedural stroke caused by thromboembolic material dislodged during CAS. Carotid angioplasty rarely is performed without stent placement.

Proposed advantages of CAS in contrast to carotid endarterectomy include the following:

- General anesthesia is not required as it frequently is for CEA

- Cranial nerve palsies are infrequent sequelae
- Simultaneous procedures may be performed on the coronary and carotid arteries

Carotid endarterectomy has a long track record, and in the hands of skilled surgeons who perform the procedure frequently, the morbidity and mortality of the procedure is small. Surgery does have certain risks that are not associated with percutaneous procedures (general anesthesia when necessary, wound infection, surgical scars), and percutaneous angioplasty with or without stenting of carotid stenosis has been proposed as an alternative to carotid endarterectomy.

In August 2004, the U.S. Food and Drug Administration (FDA) approved the first 2 stents (ACCULINK™ and RX ACCULINK™) and 2 cerebral protection filters (ACCUNET™ and RX ACCUNET™) manufactured by Guidant Corp for use in carotid arteries. The Guidant devices are indicated for combined use of a stent and DEP device to reduce stroke risk in patients at high risk for perisurgical complications from CEA who are symptomatic with >50% stenosis, or asymptomatic with >80% stenosis. Criteria to define those at high risk for CEA are specified in Guidant's Information for Prescribers (Guidant Corporation 2004). CAS with these devices for patients outside these indications is an unlabeled use.

The Guidant approved stents and filters differ in the deployment method used once they reach the target lesion, with the RX devices designed for more rapid stent and filter expansion. The Guidant devices were approved based on uncontrolled, single-arm trials and comparison to historical controls. The FDA has mandated post-marketing studies for those 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.

Other devices that have received FDA approval include the Cordis Corporation's Precise™ nitinol carotid stent and AngioGuard™ embolic protection device; ev3 Inc.'s Protégé® Stent and SpiderRX™ protection device; Medtronic Inc.'s Exponent™ carotid stent with Over-the-Wire or Rapid Exchange Delivery Systems; and NexStent's™ EndoTex Interventional Systems, used in conjunction with Boston Scientific's FilterWire EX™ or EZ™ Embolic Protection. See Approved by Governing Bodies section of this policy for dates.

Policy:

Effective for dates of service on or after January 1, 2005, Extracranial carotid angioplasty and/or stenting meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when the procedure is performed by providers and hospital facilities who **have demonstrated competence** in performing the evaluation, procedure, and necessary follow up care, in patients who are symptomatic with equal to or >50% stenosis, or asymptomatic with equal to or >80% stenosis of the extracranial carotid artery **and** who are at **high risk** for carotid endarterectomy based on the presence of **one or more** of the following:

1. Congestive heart failure-New York Heart Association Class III or IV or left ventricular ejection fraction <30%
2. Myocardial infarction within past 30 days, unstable angina, known severe coronary artery disease (left main coronary artery or 2 or more major arteries with stenosis ≥ 70%), or concurrent requirement for open heart surgery within 30 days

3. Severe chronic obstructive pulmonary disease
4. Contralateral carotid artery occlusion
5. Contralateral laryngeal nerve palsy
6. Previous radiation therapy to the neck or radical neck dissection
7. Previous ipsilateral endarterectomy with restenosis
8. Surgically inaccessible lesion (e.g. target lesion above C2)
9. Inability to move the neck to a suitable position for surgery
10. Tracheostomy

Blue Cross and Blue Shield of Alabama will cover the procedure in patients meeting these criteria when the procedure is performed by providers and hospital facilities who have demonstrated competence in performing the evaluation, procedure, and necessary follow up care. Determination of competency for purposes of coverage of the procedure will be based on published clinical guidelines that outline physician training standards and hospital facility support requirements for carotid artery stenting.

The American College of Cardiology (ACC), American College of Physicians (ACP), Society for Cardiovascular Angiography and Interventions (SCAI), Society for Vascular Medicine and Biology (SVMB), and the Society for Vascular Surgery (SVS) published a joint Clinical Competence Statement on Vascular Medicine and Catheter-Based Peripheral Vascular Interventions in August 2004. The consensus document lays out in detail the expertise a physician should have before performing carotid artery stenting: 1) extensive knowledge of carotid disease, including risk assessment, diagnosis, and alternative therapies; 2) technical proficiency in carotid angiography and stenting, including the use of special catheters, stents, and new protection devices that catch blood clots and pieces of plaque before they can circulate to the brain; and 3) the clinical skills needed to manage patient care before and after the procedure. The consensus document further outlines steps to ensure quality and patient safety as new physicians become trained in carotid stenting. It calls for extensive reporting of procedural results and ongoing analysis of patient outcomes.

Additionally, the hospital should offer a broad range of services that can treat more complex medical conditions. These hospitals are better equipped to manage complications, should they occur. Ultimately, credentialing committees at individual hospitals will decide which physicians are qualified to perform carotid stenting at their institution.

Extracranial carotid angioplasty and/or stenting does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients who do not meet the above criteria and is considered **investigational** as it has either been shown to be risky compared to carotid endarterectomy, or is still being studied in clinical trials to determine safety and efficacy.

Carotid artery stenting of the intrathoracic carotid artery does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational** due to lack of evidence of effectiveness.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether

or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The success of coronary artery angioplasty and stenting has prompted interest in other applications of this less invasive, catheter-based revascularization technique. At present, adding carotid endarterectomy (CEA) to medical management is considered a stroke prevention option in symptomatic patients with greater than 50% stenosis and less than 6% risk of perisurgical complications, and in asymptomatic patients with greater than 60% stenosis of the carotid artery and less than 3% risk of perisurgical complications. However, randomized trials comparing the outcomes of carotid endarterectomy plus medical management versus medical management alone enrolled relatively healthy patients. Further, benefit from endarterectomy may be lost if peri-procedural risk is greater than 6% in symptomatic patients or greater than 3% in asymptomatic patients. Therefore, there has been interest in carotid angioplasty and stenting (CAS) as a less invasive treatment option for higher perisurgical risk patients. (High-risk factors include severe cardiac dysfunction, requirement for combined coronary and carotid revascularization, severe renal or pulmonary dysfunction, contralateral internal carotid artery occlusion, and previous ipsilateral carotid endarterectomy or neck irradiation.) In addition, even in average risk patients, the less invasive nature of CAS and the lack of a need for general or regional anesthesia may make CAS an attractive treatment option if the short- and long-term outcomes are at least equivalent to those of carotid endarterectomy. Outcomes of particular interest include the rates of morbidity and ipsilateral stroke, measured perioperatively and at various points during follow-up, and treatment durability measured by the need for repeat interventions over the next several years.

Various authors have pointed out the need for randomized trials to further investigate the relative safety and effectiveness of the procedures. In 1998, the American Heart Association (AHA) issued a warning regarding the “premature adoption” of these percutaneous techniques. The AHA contrasted the known overall safety and efficacy of carotid endarterectomy with the uncertain morbidity and mortality of angioplasty and stenting. In addition, unlike coronary or iliac angioplasty, acute occlusion of the carotid artery associated with angioplasty or stenting may not be amenable to emergency surgical correction. Finally, the morbidity and mortality of treatment for restenosis after angioplasty and stenting are unknown. The AHA statement concluded that, at a minimum, the equivalence of percutaneous approaches to surgical carotid endarterectomy must be established in sufficiently powered, prospective randomized trials. In 2001, a consensus of opinion leaders in carotid angioplasty was published. The group concluded that CAS should not currently undergo widespread diffusion, pending results of randomized trials. Further, the group concurred that CAS is not generally appropriate for those patients considered at average risk while it might be considered appropriate for patients at high perisurgical risk when performed in experienced centers. In 2004, the AHA published consensus reports from a conference held in 2002 that affirmed their earlier position.

In October 2004, a TEC Assessment was completed on angioplasty and stenting of the cervical carotid artery with distal embolic protection of the cerebral circulation. The TEC Assessment evaluated evidence on 4 separate patient groups:

1. Symptomatic, with indication for CEA and average risk of perioperative complications;
2. Asymptomatic, with indication for CEA and average risk of perioperative complications;
3. Symptomatic, with indication for CEA and high risk of perioperative complications; and
4. Asymptomatic, with indication for CEA and high risk of perioperative complications.

The literature search for the TEC Assessment included reviews of unpublished data and data presented to the FDA. The search identified only 1 published RCT that met study selection criteria. No other direct comparisons met study selection criteria.

The TEC Assessment concluded as follows:

- The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial is the only study reported thus far that directly compares outcomes of CEA plus medical management (MM) versus outcomes of CAS with DEP plus MM. However, SAPPHIRE included no patients with symptomatic (Indication 1) or asymptomatic (Indication 2) carotid stenosis at average risk for perisurgical complications from CEA.
- SAPPHIRE also included few patients with symptomatic stenosis at high risk for perisurgical complications from CEA (Indication 3; n=96), which resulted in wide confidence intervals and differences between arms in 30-day and 1-year outcomes that were not statistically significant.
- For those with asymptomatic stenosis at high risk for perisurgical complications from CEA (Indication 4), differences in 30-day outcomes also had wide confidence intervals and were not statistically significant. While there were statistically significant differences in 1-year outcomes favoring CAS with DEP for this indication, the adequacy of 1 year's follow-up duration is questionable since durability of benefits from CAS with DEP is unknown and since the time to benefit relative to medical management is long when surgical risks are high. Furthermore, publicly available data reviewed by the FDA but not included in the published trial report suggested more frequent restenosis at 2 years in the arm given CAS with DEP.
- Early study closure resulted in fewer study patients than planned and compromised the statistical test for non-inferiority of treatments.
- Variance in differential complication rates for the two treatments across sites may have influenced results, since five of 34 sites contributed 64% of randomized patients and data were unavailable for comparison.
- Additionally, direct comparative evidence is lacking for optimal medical management alone as an alternative to adding CAS with DEP or CEA for high-risk surgical patients.
- Thus, available evidence does not permit conclusions on outcomes of CAS with DEP for any indication considered in this assessment.

The TEC Assessment conclusions differ from the FDA findings. However, the FDA based its conditional approval decision for the Guidant devices on uncontrolled, single-arm trials and comparison to historical controls.

Current Ongoing Clinical Trials

The following studies are being conducted on various stents specifically for their use in carotid arteries.

- The Carotid Revascularization Endarterectomy versus Stent Trial (CREST), sponsored by the U.S. National Institute of Neurologic Diseases and Stroke, is randomizing average risk symptomatic patients with >50% stenosis. Investigators anticipate reaching its accrual target of 2,500 randomized patients in 2006.
- The international CAVATAS phase II and European Stent Protected Angioplasty versus Endarterectomy (SPACE) RCTs also address average risk symptomatic patients. Investigators expect to report outcomes in the next 1-3 years.
- Phase II of the Carotid Revascularization using Endarterectomy or Stenting Systems (CARESS) trial will recruit both symptomatic and asymptomatic average risk patients, but is not yet open. This is a non-randomized trial that will assign patients to CAS with DEP plus MM or to CEA plus MM and may provide data to compare outcomes separately for asymptomatic average risk patients.
- SHELTER (Stenting of High-risk patients Extracranial Lesions Trial with Emboli Removal) is a single-arm prospective multicenter study designed to evaluate the potential advantage of using a carotid stent with a distal protection device as opposed to open surgery for preventing stroke. Trial enrollment was initiated in January 2001 and is expected to include 400 patients at 30 centers. This trial is part of an FDA IDE for a stent manufactured by Boston Scientific.
- The Evaluation of the Medtronic AVE Self-expanding Carotid Stent System with Distal Protection in the Treatment of Carotid Stenosis (MAVERIC) trial is initiated as a phase I study of 50 patients at 10 centers evaluating the safety and efficacy of both the self-expanding carotid stent and the GuardWire Plus system in patients with carotid stenosis who are also high-risk candidates for carotid endarterectomy. A phase II trial of 350 patients at 40 centers is planned on completion of the phase I trial.

In February 2007, an updated TEC Assessment reviewed evidence through January 2007 on angioplasty and stenting of the cervical carotid artery with embolic protection of the cerebral circulation including published registry data. No new randomized controlled trials were identified.

The TEC assessment specifically sought evidence regarding the following questions:

- Can CAS be performed with periprocedural stroke/death rates accompanied by a net health benefit among symptomatic and asymptomatic patients at average medical and anatomic risk, increase medical risk, and increased anatomic risk?
- How do CAS, CEA, and optimal medical management compare in each of these subgroups?

Eight prospective published registries reported 30-day outcomes; a single registry reported 1-year outcomes. When reported, conventional stroke/death rates ranged from 2.1% to 6.8%. In 6 of the 7 registries enrolling a substantial majority (69% to 86%) of asymptomatic patients, reported rates of stroke or death with or without myocardial infarction (MI) exceeded 5.7%. It is therefore unlikely that the periprocedural complication rate in the asymptomatic groups was

less than the 3% felt needed to accrue benefit. Three registries enrolling patients at increased medical or anatomic risk reported 30-day periprocedural complication rates according to the presence or absence of symptoms. In these registries, complication rates exceeded 3% in asymptomatic and 6% in symptomatic individuals. One registry reported periprocedural stroke/death rates in average risk asymptomatic and symptomatic patients of 3.7% and 5.7% respectively. However, considered together with results of SPACE and EVA-3S, also enrolling average-risk symptomatic patients, current evidence does not support concluding CAS benefits this group. Only CaRESS reported 1-year outcomes, including a 10.9% stroke/death/MI rate comparable to that found in SAPPHERE. A subgroup of patients from the BEACH registry considered to be at high risk owing to anatomic features had a 1.8% risk for periprocedural death or major stroke (any stroke, 3.5%). Limited evidence suggests that patients in this subgroup may be appropriate candidates for CAS.

The TEC Assessment concluded that available evidence does not support concluding that CAS is performed with acceptable periprocedural stroke/death rates for symptomatic or asymptomatic patients, that it provides a net health benefit to patients at high medical risk, or is equally effective as CEA. There is limited evidence and a clinical rationale to suggest that CAS may be beneficial in the group of patients at high anatomic risk, but present evidence has not clearly differentiated outcomes for this subgroup according to symptomatic status.

The current Cochrane Review concludes, “The current evidence does not support a widespread change in clinical practice away from recommending carotid endarterectomy as the treatment of choice for suitable carotid artery stenosis. There is a strong case to continue recruitment in the current randomized trials comparing carotid stenting with endarterectomy.”

An updated guideline on stroke prevention from the American Heart Association/American Stroke Association Council on Stroke includes recommendations on interventional approaches for patients with extracranial carotid artery atherosclerosis. The guideline affirms that CEA is the preferred treatment for patients with recent (i.e., in the past 6 months) transient ischemic attack or non-disabling ischemic stroke and severe ipsilateral carotid stenosis (between 70% and 90% of the lumen diameter), when performed by a surgeon with less than 6% perioperative morbidity and mortality. The guideline also recommends considering CEA for similar patients with moderate carotid stenosis (50% to 69% of the vessel lumen), depending on patient-specific factors age, gender, comorbidities, and severity of initial symptoms). Finally, the guideline recommends that CAS may be considered as a reasonable alternative to CEA for patients with symptomatic severe stenosis (>70%), in whom the stenosis is difficult to access surgically, or with medical conditions that greatly increase the risk for surgery, or when other specific circumstances exist (e.g., radiation-induced stenosis or restenosis after prior CEA), provided it is performed by operators with established periprocedural morbidity and mortality rates of 4% to 6%.

There are no ongoing or direct comparisons of CAS versus CEA in patients at increased risk for CEA complications. Particularly problematic is the lack of adequate data, from either randomized or non-randomized studies, to separately compare outcomes of the alternatives (CAS vs. CEA vs. current optimal medical management) in symptomatic and asymptomatic high-risk subgroups.

Major ongoing randomized trials comparing CAS versus CEA include:

- ACT I, enrolling asymptomatic patients at average risk for complications from CEA;
- CREST, enrolling both symptomatic and asymptomatic patients at average risk for CEA complications; and
- ICSS/CAVATAS-2, enrolling symptomatic patients with $\geq 70\%$ stenosis, also at average risk for CEA complications.

Medicare Policy

From March 2001, Medicare's national coverage policy restricted coverage for carotid angioplasty and stenting to patients participating in a clinical trial with Category B IDE designation from the FDA. PTA of the vertebral and cerebral arteries remained noncovered.

When FDA approved the first (Guidant) devices, Medicare coverage under the IDE trial policy was no longer available for that manufacturer's devices and was not applicable to FDA-required post-approval studies. Thus, on October 12, 2004, Medicare broadened its national coverage policy and "determined that the evidence is adequate to conclude that percutaneous transluminal angioplasty (PTA) with carotid stent placement is reasonable and necessary when performed consistent with FDA approval of the carotid stent device and in an FDA required post-approval study." For unapproved stents and DEP 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.

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 value in supporting post-approval 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 met CMS's minimum facility standards for performing carotid artery stenting for high-risk patients.

On March 17, 2005, CMS determined that CAS with DEP is reasonable and necessary for patients at high risk for carotid endarterectomy (CEA) who also have symptomatic carotid artery stenosis $\geq 70\%$. CMS limited coverage for these patients to procedures performed using 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 $\geq 80\%$, to FDA-approved Category B IDE clinical trials for unapproved devices or to FDA-required post-approval studies for approved devices. CMS defined patients at high risk for CEA as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), who would be poor candidates for CEA in the opinion of a surgeon. The list of CMS-certified facilities for CAS with DEP is now available via the CMS website. The paragraph below provides CMS' reasoning for this change in coverage policy:

“Considering the evidence and clinical situation, there appears to be sufficient evidence to infer that CAS with embolic protection can improve health outcomes for patients with severe symptomatic stenosis $\geq 70\%$ who are also at high risk for CEA, if performed with the same expertise and rate of adverse events as demonstrated in the published clinical trials. Since patients with severe symptomatic stenosis $\geq 70\%$ are at high risk for stroke, carotid interventions to reduce the risk of stroke should be considered. Although the published studies on CAS have various potential biases, we feel that the need for an alternative treatment to CEA for patients who are truly at high risk for CEA should be factored into the coverage decision, unlike the BCBS TEC report which did not consider this circumstance. By not covering this group, symptomatic patients who also are at high risk for surgery may be left with no other treatment options. The risk benefit consideration may be similarly influenced. However, having mentioned this situation, the high risk CAS studies compared CAS to CEA and found that CEA can be performed as well as CAS in a group classified as high risk. Therefore, two comparable options exist for patients with symptomatic stenosis $\geq 70\%$ who are at high risk.”

In February 2008, Brahmanandam et al, reported on a meta-analysis of 10 trials (8 randomized, controlled trials and 2 randomized) that involved 3580 patients. The meta-analysis of trials to date shows that CAS is associated with higher 30-day risk of stroke/death compared with CEA. For the patient at average surgical risk, the role of CAS is unproven, especially for symptomatic patients. And for the patient at high surgical risk, the role of any intervention is uncertain in the setting of competing comorbidities. The results of ongoing clinical trial in this area will likely provide additional evidence to support treatment choices for carotid artery stenosis. A limitation of this meta-analysis as documented by Brett, is that patient-selection criteria, operator experience, and type of stent used varied among the trials. Although randomized trials have shown that CEA is associated with better long-term outcomes in some subsets of patients with carotid stenosis, the fairly high rate of short-term adverse outcomes after both CAS and CEA reminds us of the importance of careful patient selection for any of these procedures.

Cutlip, et al (2008), recently published new results from the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) trial that compared carotid stenting using distal embolic protection vs. carotid endarterectomy in patients at high surgical risk. The group had previously reported that, in a randomized trial, carotid stenting with the use of an emboli-protection device is not inferior to carotid endarterectomy for the treatment of carotid artery disease at 30 days and 1 year. This new report issued the 3 year results. This trial evaluated 334 patients at increased risk for complications from endarterectomy who had either a symptomatic carotid artery stenosis of at least 50% of the luminal diameter or an asymptomatic stenosis of at least 80%. The prespecified major secondary end-point at 3 years was a composite of death, stroke, or myocardial infarction within 30 days after the procedure or death or ipsilateral stroke between 31 days and 1080 days (3 years). At 3 years, data were available for 260 patients (77.8%), including 85.6% of patients in the stenting group and 70.1% of those in the endarterectomy group. The prespecified major secondary end point occurred in 41 patients in the stenting group (cumulative incidence, 24.6%; Kaplan-Meier estimate, 26.2%) and 45 patients in the endarterectomy group (cumulative incidence, 26.9%; Kaplan-Meier estimate 30.3%) for an absolute difference of -2.3% for the stenting group. There were 15 strokes in each of the 2 groups, of which 11 in the stenting group and 9 in the endarterectomy

group were ipsilateral. A total of 73.8% of patients in the stenting group and 69.7% in the endarterectomy group were free of major adverse events at 3 years. A total of 80.0% of patients in the stenting group and 75.8% in the endarterectomy group were alive at 3 years. A total of 92.0% of patients in the stenting group and 93.3% in the endarterectomy group were free of stroke at 3 years. The results also showed a total of 97.0% of patients in the stenting group and 92.9% in the endarterectomy group were free of target-vessel revascularization (TVR) at 3 years.

The authors concluded that in this trial of patients with severe carotid artery stenosis and increased surgical risk, there was no significant difference in long-term outcomes between patients who underwent carotid artery stenting with an emboli-protection device and those who underwent endarterectomy. The authors noted that this data is specific to patients who are at high surgical risk, and they can provide no insight into outcomes of treatment of a carotid artery stenosis in patients at low-to-moderate risk. They also stated that on the basis of the similar long-term outcomes among high-risk patients in the two treatment groups, it may be tempting to infer that endarterectomy is preferable for lower-risk patients. However, they noted that this conclusion must await the reporting of randomized trials that are specifically designed and have adequate statistical power to address this question.

Key Words:

Carotid angioplasty, carotid stenting, endarterectomy, revascularization, ACCULINK™, RX ACCULINK™, ACCUNET™, RX ACCUNET™

Approved by Governing Bodies:

In August 2004, the U.S. Food and Drug Administration (FDA) approved 2 stents (ACCULINK™ and RX ACCULINK™) and 2 cerebral protection filters (ACCUNET™ and RX ACCUNET™) manufactured by Guidant Corp for use in carotid arteries.

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)

Exponent® Self-Expanding Carotid Stent System with Over-the Wire or Rapid-Exchange Delivery System, Medtronic vascular, Inc. (approved October 2007)

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

BellSouth/AT&T contracts: No special consideration

FEP contracts: FEP does not consider investigational. Will be reviewed for medical necessity

Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification/Pre-determination requirements: Not applicable

Coding:

CPT:

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| 0075T | Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel |
| 0076T | Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel (list separately in addition to code for primary procedure) |
| 37215 | Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection |
| 37216 | Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection |

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Policy History:

Medical Policy Group, February 2005 (4)

Medical Review Committee, February 2005

Medical Policy Administration Committee, February 2005

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Key Points Updated, FDA approval list updated, March 2008 (1)

Medical Policy Group, May 2008

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plans contracts.