

**Carotid Artery Stenting
Initial Public Comments
CAG-00085R
June 18-July 18, 2004**

Comment #1:

Submitter: Peter Fail

Organization: Cardiovascular Institute of the South

Date: June 28, 2004

Comment:

As an investigator of carotid stenting in high risk patients, I feel that coverage of these patients will become a necessity. The high risk patients not only has Carotid disease but usually a whole host of other vascular co-morbidities that makes a surgical option "high risk". There are also those patients that the surgical option is non-existent due to anatomy whether a high or low lesions or because of prior radiation or surgery, etc. The proper training will difficult to access. Even those physicians in trial some of them have low numbers. (It is assumed that their numbers to get in to the trial was adequate). I am not sure what should be considered as an "adequate" number to be considered "trained". As the trials evolved the advent of embolic protection made the procedure "safer". There have been a number of times that I found debris in a filter and was thankful for it. The clinical event may not be that different with or without filters however I would argue that any debris in the brain is bad. It may not result in a clinically evident stroke, only a memory of a friend or something else that "can't" be tested for. I feel that using the current criteria that were put forth as "high risk" by both SAPHIRE and ARCHER some be atleast the baseline that can be used as a CAS requirement for "coverage". Thank you for your consideration

Organization:

Comment #2:

Submitter: Stanley Barnwell
Organization: Oregon Health and Sciences University
Date: June 28, 2004
Comment:

The Sapphire trial and numerous other publications, as well as our own large personal experience with this technique, have shown it to be a safe and effective treatment for carotid artery disease. Approving wider indications will be beneficial to patient care.

Comment #3:

Submitter: Jon Matsumura
Organization: Northwestern university
Date: July 1, 2004
Comment:

i am a vascular surgeon in full time academic practice who does medical therapy, endarterectomy, and stenting. i think the stent procedure is the preferred treatment for some patients with carotid stenosis and should be a covered benefit. the difficulty is in defining these selected patients separately from those patients where we are not sure how CBAS compares with CEA. while it is tempting to use the sapphire, archer, or other registry entry criteria, this is impractical. many of these criteria are subjective, require other testing that may not be clinically indicated, or involve data which is not available at the time the patient decision-making occurs. the AHA policy statement recommends that symptomatic carotid stenosis be worked up and treated within a week. for example, if a patient is prepared for a stent procedure based on home oxygen, but there are no recent PFT's, should they be repeated just to document FEV1? what if the new PFT's show a better than expected FEV1, but the patient has been loaded on plavix, and now a CEA must be delayed for it to wear off? i must confess that i do not have a solution to offer, but there needs to be a "safe harbor" where clinicians and patients can act based on the information

available, and not delay therapy or perform medically unnecessary testing in order to document research-associated entry criteria. what was possible in a research study is not practical in every day clinical environment.

my second comment is in regards to training. i think there can not be too much training. what may have worked (or failed depending on your opinion) in 1999 with AAA endografts, is not enough in 2005. of course, every specialty also has their "dibs" and exclusionary suggestions. my suggestion is that you let the societies determine criteria for their own specialty, but then hold them to audited results--like liver transplantation. if a clinician doesn't meet certain thresholds, then they don't get reimbursement.

Comment #4:

Submitter: Malcolm Foster

Organization: ETHC/BHET

Date: July 2, 2004

Comment:

Our practice has been involved with carotid stenting since 1997. We have treated several hundred patients. Costs have been low, compared to endarterectomy. Outcomes have been excellent, with few complications, lower than the published rates. From our experience carotid stenting should be the procedure of choice to prevent stroke in high risk patients. Please extend coverage to appropriate medicare patients.

Comment #5:

Submitter: Angelo Makris

Organization: Midwest Heart Specialists

Date: July 2, 2004

Comment:

The SAPPHERE trial clearly proves superiority of Carotid Stenting compared to Carotid Endarterectomy in high risk patients. The FDA panel agrees. It is up to Medicare to take note of these results and issues and approve

coverage. Medicare patients would be poorly served if they are high risk and have to go for endarterectomy instead of stenting.

Comment #6:

Submitter: Russell Rotondo
Organization: East Tennessee Heart Consultants
Date: July 2, 2004
Comment:

I agree that National coverage for carotid stenting should be extended to the populations requested.

Comment #7:

Submitter: Gregory Mishkel
Organization: Prairie Cardiovascular Consultants
Date: July 5, 2004
Comment:

I am writing as a busy interventional cardiologist, who has participated in IDE trials of carotid stenting from the original Wallstent trial on through the NIH CREST trial. I was the local PI for both the Sapphire, BEACH & Archer trials.

I believe the weight of evidence from these clinical trials demonstrates that CAS is at least as effective as CEA, but can be performed in high risk populations with less cardiac morbidity, and clinically acceptable risks (no difference with respect to minor/major strokes). The cumulative weight of multiple studies now supports the clinical release and reimbursement for this procedure. Within my own practice many patients have benefitted via reduction in subsequent strokes and hopefully with clinical release, others will have access to this durable procedure.

The clinical rationale for approval is quite simply that surgical endarterectomy is often prohibitively risky for many patients or indeed may not be possible without considerably increased risk. Many patients are either too old (age>80) or have so many medical comorbidities

which may compromise their postoperative course (advanced cardiac disease, severe pulmonary insufficiency, uncontrolled hypertension are probably the most common). Many anatomical features add risk to surgery, and these include previous neck irradiation, a contralateral carotid occlusion or laryngeal nerve palsy, previous ipsilateral failed endarterectomy and a high carotid lesion above the angle of the jaw) or the need for concomitant cardiac surgery. Clearly as this procedure moves from the realm of investigation (and usage by high volume operators) to the clinical arena, care will have to be paid to appropriate indications and training. I believe that evidence supports the use of CAS in high risk symptomatic patients with >60% stenosis and asymptomatic patients with >80% stenosis. Operators should be well versed in the field of peripheral interventions, and will come from the disciplines of neurosurgery, cardiology, radiology and vascular surgery. It is imperative that they have a wide variety of technical skills to include knowledge of carotid anatomy and cerebral physiology as well as hands on skills with guiding catheters and small wires as well as embolic protection devices. Potential operators will have to have facility managing the hemodynamic and cardiac instability which may follow CAS, as well as have access to an interested neurologist and radiologist for post procedural evaluations if necessary. Initial training can be provided via didactic learning on line or through printed material. Ultimately potential operators will have to travel to regional training centers for technical education. Personally I believe that the procedure should be restricted to high volume cardiac or vascular centers. In the endarterectomy literature, it is well established that there is increasing mortality and morbidity relative to a sites endarterectomy volume. I have committed 9 years of my professional life to participating in FDA/IDE trials and has shepherded this program through our my own medical community and IRB, I am quite concerned about the potential for

practitioners to take commercially available systems "off the shelf" and cobble together a carotid stent program without appropriate training or oversight once this procedure becomes "commercially available". There are very substantial economic/competitive forces at play between individual practitioners, hospitals and specialities here that could destroy the field, and very adversely effect patient outcomes. For the last decade I have been involved in training predominantly cardiologists, but also vascular surgeons in advanced vascular interventions, and although the vast majority are thoughtful, competent and well intentioned, it is incomprehensible to me that all of them are going to be capable of safely performing this procedure in a widespread capacity.

Comment #8:

Submitter: Harvey M. Wiener, DO, FSIR, FCIRSE, FAHA

Organization:

Date: July 1, 2004

Comment:

Dear Dr. Chin -

I am an Interventional Radiologist with sixteen years experience practicing in Phoenix, Arizona. I applaud the deliberations by your organization in reference to Carotid Artery Stenting. While I have not participated in any clinical trails, I have personally performed thousands of carotid arteriograms and placed thousands of stents in a multitude of arteries.

This new technology is unique as it may ultimately supplant carotid endarterectomy; a mainstay procedure of the Vascular Surgeon. The downside is that patients may be harmed by those that will perform this procedure without adequate training or an appropriate knowledge base. If you haven't already done so, I would like to refer you to the Journal of Vascular and Interventional Radiology, October 2003, in which a position paper was published about the topic of carotid intervention and the need for appropriate training and credentialing guidelines. In addition, the American Society of Interventional and Therapeutic Neuroradiology is holding its first annual meeting this summer and will include a 16 hour CME course on carotid intervention, patient selection, and problem solving (www.asitn.org <<http://www.asitn.org/>>). The ASITN has worked closely with

the Society of Interventional Radiology (www.sirweb.org <<http://www.sirweb.org/>>) to make this course a foundation for those physicians who desire to perform carotid intervention.

While the device manufacturers will be required to provide training on their products, CMS/HHS may want to consider that physician operators also demonstrate an appropriate knowledge base prior to undertaking care of these patients. It may also be essential to consider how the manufacturer will train the operator. For example, the Guidant Corporation has considerable experience in physician training based on their aortic stent graft experience. The Cordis Corporation, while an excellent company, has limited experience in physician training. The aforementioned journal article and CME course may provide you with solid, unbiased information about some of the ancillary issues that need to be considered prior to inserting a stent into a carotid artery. A deliberate plan, orchestrated in concert between CMS/HHS and the device manufacturers will only benefit patient safety and the ultimate total acceptance of this procedure as the standard of care for patients with carotid stenosis.

Thank you for your time and consideration. I would be happy to continue a dialogue with you, if you think it appropriate.

Harvey M. Wiener, DO, FSIR, FCIRSE, FAHA

Comment #9:

Submitter: Scott Smith
Organization:
Date: July 6, 2004
Comment:

Based on the clinical data on carotid stenting, I feel CMS should reimburse carotid stenting.

Comment #10:

Submitter: Mark H. Wholey, M.D. and Roseanne R. Wholey
Organization: Pittsburgh Vascular Institute and Roseanne R. Wholey and Associates
Date: July 14, 2004
Comment:

Dr. Steve Phurrough c/o Rana Hogarth
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Mail Stop C1-09-06
Baltimore, MD 21244

Dear Dr. Phurrough,

We are interested in providing our comments for carotid artery stenting procedures (CAG-00085R).

Regarding the topics that we viewed on the tracking sheet our responses are as follows:

Definition of patients at "high risk" for carotid endarterectomy:

The subset of patients with a high risk from surgery includes patients who have had prior endarterectomy and present with restenosis, patients who have had laryngeal nerve damage from prior surgery, or who have a history of radiation therapy to the head/neck, or who have high grade stenosis in one carotid artery and total occlusion of the opposite. Octagenarians are high risk. Patients with renal failure or patients who need urgent bypass surgery, patients with unstable angina, and patients with any other significant comorbidities. The trial patients all had 80% stenosis or greater.

Provider qualification and training:

Providers have to be experienced interventionists who have performed at least 100 diagnostic arteriograms. To be credentialed you would have to have participated in the trials or have experience with at least 25 carotid stents with favorable outcomes with less than 5% peri-procedural stroke.

Efficacy of embolic protection devices:

The literature in the trials support the efficacy of embolic protection devices and procedures should not be done without them unless there is a rare case where it is technically not possible to deploy and carotid stenting is mandatory.

Results from other carotid stenting trials:

The carotid stent trials have met their endpoints and have shown equivalency or non-inferiority to endarterectomy. The randomized SAPPHERE trial had event rates that were superior to carotid endarterectomy in several parameters namely peri-procedural and one year stroke event rates, myocardial infarction, cranial nerve palsy, and procedural bleeding. Archer met its non-inferiority end point against historic weighted control studies. Without question it is appropriate for the high risk patient population. If one looks at the diabetic population high risk subset there is clearly a significant difference in stenting vs. endarterectomy.

Degree of facility experience:

Trained personnel for peripheral vascular procedures (including physicians, technical staff and lab facilities) are necessary.

Types of provider training programs to be developed:

On-line didactic training programs prior to participate at an educational carotid center where case discussion, techniques and patient selection is thoroughly discussed, followed by taped or live case presentations and finally proctoring of the trainee in his own laboratory.

Supporting staff and specialty requirements:

All procedures should be screened by a neurologist and preferably a stroke neurologist. Periodic post procedure follow-up should occur at 30 days, 6 months and one year.

Stipulations in place to ensure appropriate use:

Procedural outcome analysis similar to what existed in the trials.

Thank you for considering our comments. Hopefully the outcome will be a complete overturn of the national non-coverage policy established in 1984 with reimbursement of the new 2005 stent codes at a rate similar to that of carotid endarterectomy.

Sincerely,

Mark H. Wholey, M.D.
Chairman Pittsburgh Vascular Institute

Roseanne R. Wholey
President, Roseanne R. Wholey and Associates

Comment #11:

Submitter: Barbara Calvert

Organization: Guidant

Date: July 15, 2004

Comment:

Guidant Corporation welcomes the opportunity to comment on the reconsideration of coverage for carotid artery stenting (CAS) by CMS. Guidant fully supports modification of the current national policy to permit coverage of carotid stenting for patients at "high risk" for carotid endarterectomy (CEA). Our comments will address information requested by CMS in the NCA tracking sheet including the definition of high-risk patients, results of the ARChER clinical trials, the efficacy of embolic protection systems, and provider qualification and training.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research facilities in the states of Minnesota, California, and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leader in the research, development, and manufacturing of medical technologies primarily in treatment of cardiovascular and vascular illnesses.

Definition of High-Risk Patients

Guidant recommends that CMS revise the current coverage policy [Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (#CAG-00085A)] as follows:

Coverage shall include the high-risk patient as defined by clinical evidence:

- Carotid stenosis $\geq 50\%$ and recent neurological symptoms referable to the lesion or stenosis $\geq 80\%$ without recent neurological symptoms
- Significant co-morbidities: examples but not limited to coronary, renal, and pulmonary diseases, uncontrolled diabetes or angina, essential hypertension
- Anatomical factors precluding surgical access or increasing surgical risks
- Restenosis of prior CEA or other previous neck surgeries
- Contralateral carotid occlusion

Clinical Evidence Supporting Coverage

Guidant believes that evidence from the ARCHeR, SAPPHERE, and other high-risk carotid stenting trials clearly demonstrates the benefit of CAS coverage for patients at high risk for surgical treatment. Guidant sponsored the ARCHeR (ACCULINK™ for Revascularization of Carotids in High Risk patients) Trials. Inclusion criteria, rigor, 30-day data and 12-month clinical results and protocols were presented to the Coverage and Analysis Group August 2003 and April 2004. Therefore, the following only summarizes the clinical evidence.

Overview of ARCHeR Trials

Guidant's ARCHeR Trials (ARCHeR 1, 2, and 3) were a series of three prospective, non-randomized, multi-center clinical trials of patients deemed at high-risk or unsuitable for CEA. The ARCHeR trials were conducted to evaluate the safety and effectiveness of CAS using the ACCULINK™ Carotid Stent System and the ACCUNET™ Embolic Protection System (EPS) for the treatment of carotid artery disease. These patients were considered at high risk for CEA due to the presence of surgical/medical co-morbidities or anatomy unfavorable for CEA. Of the 657 enrolled patients, 73% of participants were Medicare beneficiaries.

Objective:

The objective of the ARCHeR trials was to establish non-inferiority of carotid stent therapy using ACCULINK with or without ACCUNET in high-risk patients to an historical control of the standard of care (CEA and/or medical management) in a similar patient population. The primary endpoint was a composite of 30-day death, stroke, and MI, plus ipsilateral stroke to one year. The comparative outcome rates for the standard of care were derived from analysis of the literature on CEA and medical therapy, and are

defined as the “weighted historical control (WHC)”. The WHC comparison rate for ARChE_R 1 and 2 was 14.5%. ARChE_R 3 evaluated a modified delivery system and was designed to show equivalence with the results in ARChE_R 2 at 30-days.

Inclusion criteria:

Inclusion criteria and stent design were identical in all trial phases.

However, ARChE_R 1 did not include the ACCUNET. ARChE_R 2 and 3 both included the EPS device with only a modification in the delivery system for ARChE_R 3.

Patients with a recent neurological event and stenosis $\geq 50\%$ by angiography or asymptomatic patients with stenosis $\geq 80\%$ by angiography were eligible. Patients enrolled were required to be at high risk for surgery based on the presence of one or more medical or surgical co-morbidity or unfavorable anatomical features. Medical/surgical co-morbidities included significant coronary disease, pulmonary disease, renal failure, uncontrolled diabetes,

restenosis after previous CEA, unstable angina or contralateral occlusion. Unfavorable anatomy included post-radical neck surgery, surgically inaccessible lesions, and contralateral laryngeal nerve palsy. Most characteristics would have excluded the patient from earlier CEA trials such as NASCET and ACAS. Nearly 86% of patients met criteria for medical/surgical co-morbidities; the remainder were categorized as anatomy not favorable for CEA.

Primary Endpoint Results for ARChER 1 and 2:

The endpoint was a composite of all death, stroke, MI at 30 days plus ipsilateral stroke between 31 days to 1 year. The study hypothesis of non-inferiority (equivalence) in a high-risk population was proven since the composite endpoint rate at 365 days was less than the 14.5% WHC in both ARChER 1 (8.3%) and ARChER 2 (10.2%).

Primary Endpoint Results for ARChER 3:

The ARChER 3 composite of all death, stroke, and MI at 30 days (8.3%) was non-inferior (equivalent) to the rate observed in ARChER 2 (8.6%).

Hierarchical Data	ARChER 1 N = 158	ARChER 2 N = 278	ARChER 3 N = 145
30-day event rates			
Major and Fatal Strokes	1.9%	1.4%	1.4%
Death & All Strokes	6.3%	6.8%	7.6%
Death / All Stroke / MI	7.6%	8.6%	8.3%
Composite Endpoint rates vs WHC of 14.5% for ARChER 1 and 2			
30-day death, stroke and MI, plus ipsilateral stroke between 31 and 365 days	8.3%	10.2%	N/A

Summary:

Results from the ARChER trials have demonstrated that the ACCULINK Carotid Stent System and the ACCUNET EPS are safe and effective in treating carotid artery disease for patients with high-risk surgical/medical and anatomic co-morbidities.

Efficacy of Embolic Protection (EP)

The purpose of EP is to capture debris that may be dislodged during a stenting procedure. During the ARChER 3 clinical trial, the ACCUNET™ EPS deployed in all but 2 cases. Of 136 devices examined by the pathology core lab, 58% of the baskets collected atherosclerotic debris of various types. The summary pathology report from Armed Forces Institute of Pathology Chairperson, Renu Virmani M.D. concluded “the ACCUNET™ filter device appears to be effective for safeguarding distal cerebral vasculature from potentially harmful embolic debris during invasive procedures in carotid arteries. ... The average particle area was

0.04-mm², which, if left alone, could place the distal cerebral tissue at risk for ischemia/necrosis.” There was no statistical difference between composite death/stroke/MI endpoints of the ARChE trials with or without embolic protection. The three ARChE trials were not powered or designed to show a difference between CAS with or without EP. We anticipate EP will be used in the majority of cases unless it is technically unfeasible or judged to have undue patient risk.

Training

The Guidant plan for provider device training was presented to the CMS Coverage and Analysis Group on May 27th and Guidant is considering CMS suggestions for incorporation into the final plan. Discussions with the FDA regarding this post-approval training program should be finalized by the end of July 2004.

The Guidant training plan will include a controlled release of ACCULINK and ACCUNET to specific physicians and hospitals. Physician training will be in three levels. Level 1 is for physicians who gained experience in Guidant carotid clinical trials and will focus on an updated device training and approved indications. Level 2 training will be for providers who participated in non-Guidant clinical trials and/or were trained via approved training programs by other carotid device manufacturers and have experience with their devices. The Level 3 program will be for physicians with extensive endovascular experience but minimal experience in carotid artery stenting. Level 3 training agenda includes didactics, case reviews, performing cases on simulators, and hands-on experience via anatomical models. Upon completion, physicians will receive documentation of participation. Hospitals will also be educated on the stent system, approved indications, and the procedure prior to release of product to their site. A Guidant carotid trained field representative will be present to support the first three cases and additional cases at the request of the physician.

Conclusion

Given the strong clinical evidence supporting the benefits of carotid stenting, widespread support in the medical community, and the critical need for endovascular treatment options for Medicare beneficiaries, we urge CMS to act expeditiously and implement CAS coverage for Medicare beneficiaries at high risk for surgical treatment.

We also request that CMS take steps to assure adequate inpatient CAS payment concurrent with coverage. Specifically, we recommend that CMS consider, on an interim basis for FY 2005, assigning to DRG 533 (Extracranial Vascular Procedures with CC) all carotid stenting cases that otherwise could have been paid under the DRG pair 533/534. Adequate payment is essential to ensure patient

access following FDA approval and coverage and for ongoing carotid stenting clinical trials.

Please let us know if you have questions or require additional information.

Comment #12:

Submitter: Gary M. Ansel, MD
Organization: Riverside Methodis Hospital
Date: July 18, 2004
Comment:

I would like to comment on the coverage for carotid stenting. I and my two partners have been active in this field since the early Wallstent Trials. We have participated in every FDA trial to date.

Definition of high risk

Procedural = previous neck radiation, previous carotid endarterectomy or lateral neck surgery, bilateral disease, contralateral occlusion, altered anatomy of surgical access site, difficult surgical access, high cervical lesion, intra-thoracic lesion

Significant comorbidities = 2 vessel coronary disease with either angina or ischemia on noninvasive testing, COPD, CHF, need of abdominal or thoracic surgery within 30 days, advanced age >75 years old.

Provider qualification and training= Having trained other individuals from multiple specialties the

common denominator is catheter skills. No matter the specialty preceeding catheter skills by training or experience allows for learning the procedure.

Metrically controlled testing of cognitive and procedure performance must be demanded due to the varied specialties to undertake this procedure.

From a cognitive standpoint the physician should undergo an extensive training module in carotid disease and management prior to approval.

Efficacy of embolic protection: Though the first 125 procedures performed at our institution were

not associated with a neuro event (neurologist controlled) patient selection was utilized. Since the use of embolic devices we have been less restrictive on our patient selection with the same results. We visually find debris in approximately

25% of the devices. Some of these debris are quite large and undoubtedly would have been associated with severe neuro compromise. The world carotid registry we are involved in has shown a consistent decrease in neuro events since the addition of the devices. The new protection devices I feel will allow for even less risk as they are smaller and easier to utilize.

Evidence of efficacy and appropriateness of the procedure: The SAPPHIRE trial clearly demonstrates both immediate decreased risk as well as increasing benefit over surgery periprocedurally as well as at the 1 year time frame. This trial did not even include the intrathoracic common carotid lesions that are now not treated surgically due to the high risk and invasive nature of the surgical treatment which is offset by the relative ease of stenting.

Degree of facility experience: Though we started with a multispecialty approach this was out of fear strokes and the perceived need for the potential need of rescue procedures for distal emboli. This has not been the case. Our institution has never needed to perform surgical rescue and have dropped the multispecialty requirement. As stated previously catheter skills are a common denominator for successful procedure learning and allow for low risk institution of the procedure. We do feel that an extensive training program is needed for institution of this procedure. Previous cerebral vascular angiography training does not appear necessary and can be instituted into the carotid stent training.

Neurology consultation must be available on site to allow for successful program initiation.

Types of training: Due to the multiple specialties involved, all with their own deficiencies I would recommend that a comprehensive program with metrics on cognitive and procedural aspects be tested. Training to only the device will not be sufficient for physicians.

Supporting Staff: The supporting staff should be trained on neurological patient assessment as

well as on the device.

Stipulations: Providers should be required to successfully complete industry training as well as have a

primary catheter based practice. This would require endovascular credentials at their institution.

Comment #13:

Submitter: Stephen F. Daugherty, MD, FACS, RVT

Organization: Clarksville Surgical Associates, PLC

Date: July 18, 2004

Comment:

I write to you as a private vascular surgeon with a long and broad experience performing endovascular procedures in multiple vascular beds. The hospital in which I practice has four vascular surgeons on staff, all of whom are skilled and experienced with complex endovascular procedures, the most common of which are angioplasty and stenting procedures. We perform carotid endarterectomy (CEA) on a regular basis and we have a modest experience performing carotid angioplasty/stenting (CAS).

PATIENT SELECTION

I am very eager for carotid stenting to become available for my patients who I consider high risk for CEA. The initial clinical trial results are convincing even to many of the most reluctant vascular surgeons that we should be using CAS for selected patients who are at high risk for CEA. I am troubled that we cannot yet offer the technology to carefully selected patients who I deem to be better served by CAS. High risk patients include:

- Severe chronic obstructive pulmonary disease
- Ischemic heart disease with baseline ischemia
- Recurrent carotid stenosis
- History of neck irradiation or ipsilateral radical neck dissection
- Severe congestive heart failure
- Common carotid or internal carotid artery stenosis in locations not accessible through the standard neck incision

As you know, data from trials of CEA versus medical therapy have supported CEA for patients with a greater than 50% carotid stenosis who are

symptomatic for ipsilateral carotid embolic events and for patients who have a greater than 80% stenosis and are asymptomatic. I believe this group of patients should be considered for CAS if they have one or more of the risk factors listed above.

PROVIDER QUALIFICATIONS AND TRAINING

CAS should be performed only by physicians who have considerable experience performing endovascular procedures in the non-coronary vascular beds such as the iliac, renal, subclavian, upper and lower extremity, and mesenteric arteries. The skill sets required for performing carotid arteriograms and for CAS are all identical or only minimally different from the skill sets possessed by experienced endovascular physicians. Only very modest additional hands-on training is necessary for a skilled endovascular physician to safely perform CAS. While some will encourage you to require a large volume of CAS experience in an effort to impede other skilled endovascular physicians from providing the service to their patients, the emphasis should be on assuring that the physician has a broad range of endovascular skills and experience which transfer very easily to performance of CAS. I believe that a physician should have an absolute minimum of 100 major non-coronary endovascular procedures as a prerequisite to training for CAS.

Provider training by means of a didactic course with sophisticated simulator training and a short hands-on course in CAS should be adequate for physicians who **ALREADY POSSESS A HIGH LEVEL OF ENDOVASCULAR SKILLS.**

A basic prerequisite to performing CAS is thorough knowledge of cerebrovascular disease, the ability to evaluate the patient clinically, and to interpret relevant vascular ultrasound, arteriograms, and other cerebrovascular imaging techniques. The physician must be able to evaluate treatment options thoroughly and to provide appropriate long-term follow-up for the patient. A physician who is not able to provide this evaluation and long-term follow-up should not be doing the procedures. The long term follow-up is essential to assess early and late complications of the procedure and to detect recurrent stenosis or contralateral disease in a timely manner.

Physician training should include didactic training and review of:

- Patient selection criteria,
- Clinical and anatomic indications for CEA or CAS,
- Device selection and use,
- Perioperative care,
- Management of complications,
- Troubleshooting of device or equipment malfunctions,

Short and long term follow-up of patients.

FACILITY QUALIFICATIONS

A facility planning to do CAS should use a high-quality fixed digital fluoroscopy unit with a C-arm capable of providing multiple views of the cerebrovascular anatomy. Staff circulating or scrubbing for the procedure should possess excellent knowledge of the various endovascular devices which might be used in a complicated case. A facility experience of at least 100 non-coronary endovascular procedures per year is desirable before undertaking CAS. Hospital staff need specific exposure to the CAS devices and training in preparation and use of the devices.

SPECIALTY REQUIREMENTS

Historically, vascular surgeons evaluate patients with carotid artery disease and make decisions with the patients regarding medical or surgical management; vascular surgeons also provide long term follow-up of patients who do not have severe enough disease to undertake surgery and for post-op CEA patients. Vascular surgeons routinely evaluate their patients neurologically on many occasions during the course of their care and follow-up and, in most cases, do not need other specialties for routine care. Nonetheless, patients who have carotid disease often have coronary artery disease and high risk patients for CEA who are to undergo CEA or CAS should have a consulting cardiologist available should they be needed.

We believe strongly that a patient who is under consideration for CAS should be evaluated by a vascular surgeon as part of the pre-op work-up to assure that both options of CEA and CAS are presented to the patient who must decide which procedure to request. There is legitimate concern that some patients may be encouraged to undergo a specific procedure because it is the only option a particular clinician can offer. Some vascular surgeons will only be able to offer CEA, but most will be able within the next several years to offer CEA or CAS to appropriate patients. Physicians in other specialties will be able to offer only CAS. This will become an even larger issue if CAS proves to be a reasonable alternative to CEA in moderate risk patients.

In conclusion, some of our patients need the CAS technology available to them; the physicians and facilities providing the services need to be experienced and skilled with non-coronary endovascular procedures before undertaking training to perform CAS. Thank you for your review of these comments.

Comment #14:

Submitter: Gregorio Sicard
 Organization: Society for Vascular Surgery
 Date: July 18, 2004
 Comment:

The Society for Vascular Surgery (SVS) represents 2,000 vascular specialists in the United States. Our society has 40-years experience in the evaluation and treatment of extracranial cerebrovascular disease. SVS members have participated in all major carotid endarterectomy and carotid stent trials performed in the United States and Canada. Importantly, SVS represents the only specialty society with a substantial proportion of members who are *experts at both treatment options*, open carotid endarterectomy and carotid stenting. This provides SVS a uniquely objective perspective to address the coverage issue. SVS offers the following comments regarding reconsideration of the Medicare National Coverage Policy for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting (CAG-00085A, dated March 19, 2001).

SVS did not favor Medicare coverage for carotid stenting in prior years because published safety and efficacy data were mostly from single centers. There were no multicenter prospective trials comparing carotid stenting to the standard of practice, carotid endarterectomy (CEA). In contrast, CEA has been one of the most studied surgical operations in the world over the past 3 decades, and large prospective trials of CEA vs. medical therapy continue to be published. SVS now believes that data collected under auspices of SAPHIRE, CREST (lead-in data), and CARESS trials provide sufficiently convincing safety and efficacy information on carotid stenting (CS) to allow expansion of coverage to the Medicare beneficiaries in certain high-risk categories. SVS would like to offer the following comments and recommendations for Medicare coverage of carotid stenting in specific proposed high risk indications, based on (1) our interpretation of the available data comparing safety and efficacy of CS to CEA, and (2) our collective judgment regarding superiority of these therapies over medical treatment. Please note that in the following table, the definition of “symptoms” is limited to clear-cut lateralizing hemispheric transient ischemic attacks, unilateral transient monocular blindness and non-disabling strokes.

Risk Factor	Symptoms?	Carotid Stenosis	Indication / Comments	SVS Support
Previous CEA with recurrent stenosis	Symptomatic	>50%	CEA perioperative complication rate above baseline	YES
Previous CEA with recurrent stenosis	Asymptomatic	>80%	CEA perioperative complication rate above baseline	YES
S/P radiation therapy to neck	Symptomatic	>50%	CEA perioperative complication rate above baseline	YES

S/P radiation therapy to neck	Asymptomatic	>80%	CEA perioperative complication rate above baseline	YES
Contralateral laryngeal nerve palsy	Symptomatic	>50%	CEA carries low incidence of catastrophic bilat laryngeal nerve palsy	YES
Contralateral laryngeal nerve palsy	Asymptomatic	>80%	CEA carries low incidence of catastrophic bilat laryngeal nerve palsy	YES
Contralateral carotid occlusion	Symptomatic	>50%	Literature supports higher stroke risk than baseline for CEA	YES
Contralateral carotid occlusion	Asymptomatic	>80%	Literature supports higher stroke risk than baseline for CEA	YES
Cervical ICA lesion above C2	Symptomatic	>50%	Difficult surgical access	YES
Cervical ICA lesion above C2	Asymptomatic	>80%	Difficult surgical access	YES
Intrathoracic Carotid lesion	Symptomatic	>50%	Surgery requires thoracotomy	YES
Intrathoracic Carotid lesion	Asymptomatic	>80%	Surgery requires thoracotomy	YES
Pulmonary disease documented FEV1<30%	Symptomatic	>50%	CEA may be associated with increased pulmonary complications	YES
Pulmonary disease documented FEV1<30%	Asymptomatic	>80%	CEA may be associated with increased pulmonary complications	YES

Risk Factor	Symptoms?	Carotid Stenosis	Issues / Comments	SVS Support
Open heart surgery required within 2 wks	Symptomatic	>50%	CEA may be associated with increased perioperative cardiac complications	YES
Open heart surgery required within 2 wks	Asymptomatic	>80%	CEA may be associated with increased perioperative cardiac complications	YES
Documented NYHA Class	Symptomatic	>50%	CEA may be associated with increased perioperative	YES

III or IV CHF and documented LVEF<30%			cardiac complications.	
Documented NYHA Class III or IV CHF and documented LVEF<30% and life expectancy > 5 years	Asymptomatic	>80%	CEA may be associated with increased perioperative cardiac complications. More data would be useful to demonstrate superiority over medical therapy.	YES
Recent MI <4 weeks	Symptomatic	>50%	Elevated cardiac risk for CEA. Medical treatment for symptomatic carotid lesion not adequately efficacious	YES
Recent MI <4 weeks	Asymptomatic	>80%	Need more data. Medical treatment may be best option until cardiac status stabilizes	NO
Unstable angina documented CCS class III/IV	Symptomatic	>50%	Elevated cardiac risk for CEA. Medical treatment for symptomatic carotid lesion not efficacious	YES
Unstable angina documented CCS class III/IV	Asymptomatic	>80%	Elevated cardiac risk for CEA, but need more data needed to demonstrate CS superiority over medical therapy.	NO

Risk Factor	Symptoms?	Carotid Stenosis	Issues / Comments	SVS Support
Severe tandem lesions	Symptomatic	>50%	Literature does not indicate CEA is high risk in this setting. Nature & severity of second lesion lack definition	NO
Severe tandem lesions	Asymptomatic	>80%	Literature does not indicate CEA is high risk in this setting. Nature & severity of second lesion lack definition	NO
Age > 80 yrs	Symptomatic	>50%	CREST lead in data shows elevated stroke risk for stent. Need more data before approving stent	NO
Age >80 yrs	Asymptomatic	>80%	CREST lead in data shows elevated stroke risk for stent. Need more data before approving stent	NO

SVS would like to emphasize that our goal is to endorse carotid stenting as a covered treatment option for those specific high-risk patient subsets in whom CS is proven equivalent to CEA, but as noted in our table, we believe some proposed high-risk subsets require more investigation. Withholding stent treatment from individuals who would benefit is as undesirable as allowing it for subsets who don't meet these criteria, and we encourage CMS to revisit any coverage decisions that are made as more high quality data become available.

Although noninvasive methods including quality-controlled carotid duplex ultrasound, MRA, CTA, and CTA with three-dimensional reconstructions are diagnostic techniques suitable for entry in a carotid treatment algorithm, all patients undergoing carotid stent will necessarily have an ipsilateral diagnostic carotid arteriogram as an initial step. For standardization purposes of inclusion under this policy, we recommend that the final determination of carotid stenosis required for CS coverage must be calculated from the angiographic images using the methodology defined in NASCET.

SVS wishes to address a second crucial issue, which is the absolute need for CMS to monitor delivery of this new therapy to individuals proven to derive benefit. We are extremely concerned that carotid stenting will be offered to a wide range of individuals falling well outside proven indications. Carotid stenting indications that we endorse are based on tested "high-risk" indications, either anatomic or medical. *For "normal-risk" patients we believe it is absolutely crucial to withhold coverage until prospective randomized studies such as CREST have tested the equivalence of CS to CEA.* We

cannot overemphasize the importance of continued data collection, powered sufficiently to test appropriateness of expanded and subset indications with independently adjudicated medium and long-term outcome data. We understand that the task of assuring appropriate application of the new CS technology on a patient-by-patient basis will be a challenging task, but we believe CMS has the skill to execute accurate monitoring, the power to ensure compliance, and the obligation to do so. For instance, post-payment audits could be conducted at medical centers where the frequency of CS compared to CEA far exceeds expectations.

Carotid stenting is an exciting new treatment modality. We urge CMS to consider all available data during reconsideration of the current non-coverage policy, and we are entirely willing to meet with members of the Agency at any time should you believe our expertise in cerebrovascular disease may be helpful. We appreciate the opportunity to submit comments.

Comment #15:

Submitter: Boston Scientific Corporation

Organization: Boston Scientific Corporation

Date: July 16, 2004

Comment:

BY ELECTRONIC SUBMISSION

July 16, 2004

The Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850

ATTN: Joe Chin MD

RE: (CAG-00085R) Coverage Request to Revise Current Policy

Dear Dr. Chin:

Boston Scientific Corporation (Boston Scientific) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS's) Notice of Review of Coverage for Carotid Artery Stenting (CAG-00085R). We are pleased CMS has decided to revisit this important policy matter and encourage the Agency to revise its current policy in order to extend coverage beyond FDA Category B IDE designated clinical trials. Toward that end, we offer the following comments on some of the questions posed in the Notice.

Definition of Patients at "High Risk" for Carotid Endarterectomy

We believe that there are a significant number of similarities between the trials that examined/are examining the safety and efficacy of stents to treat stenosis of carotid arteries. We encourage the Agency to build on this substantial consensus and include the full range of the patient inclusion/exclusion criteria utilized in these trials to define patients at high risk for surgery (carotid endarterectomy).

A number of the criteria that were used to define high risk patients in the BEACH, ARCHER, SAPPHIRE, CABERNET and other clinical trials are similar, and to the extent there were additional criteria, there were minor variations in them. The criteria that were utilized in all trials include the following items.

Altered Anatomy:

- Total occlusion of contralateral carotid artery
- Previous radiation treatment to neck or neck dissection
- Treatment lesion at or above 2nd vertebral body C2
- Restenosis of a previous CEA
- Laryngeal nerve palsy
- Target lesion below clavicle or C2
- Inability to extend head

In addition the majority of the trials included Tracheostomy or tracheal stoma.

Complicating co-morbid conditions:

- Heart Failure defined by LVEF<30%
- CHF, NYHAA Class III/IV
- MI within previous 6 weeks or defined as acute
- TIA within 180 days
- Patient on anti-coagulants (Warfarin)
- Unstable Angina
- Uncontrolled Diabetes
- Patient requiring CABG, cardiac valve or peripheral vascular surgery or abdominal aortic aneurysm repair
- Asymptomatic patients greater than or equal to 80 percent of stenosis on angiographic results.
- Symptomatic patients greater than or equal to 50 percent stenosis on angiographic results.

In addition, the majority of the trials included: COPD qualified as moderate to severe; dialysis dependent renal failure; two or more proximal major coronary arteries with greater than 70% stenosis at the time of the index procedure.

Age:

- Minimum requirement on age was 70years of age or greater. (Some trials age requirement was 80 years of age.)

Multiple or Bilateral lesions:

- Multiple or tandem lesions
- Bilateral stenosis

Provider Qualification and Training

Boston Scientific believes it is important that the Agency recognize the overall effectiveness that established entities and procedures have played in ensuring that health professionals and institutions competently provide care. While carotid artery stenting (CAS) is a significant procedure, there is no reason why these established entities and procedures will not protect the public health. CMS should not duplicate their efforts, nor impose additional regulation on the practice of medicine in this area. By doing so, the Agency will help to ensure that beneficiaries have timely, geographically reasonable and appropriate access to this procedure.

Whether considering the role of FDA in ensuring that manufacturers have an appropriate training program to ensure that physicians and staff can safely use a device, the role of specialty societies in setting competency standards for their members, the ability of local hospital credentialing committees to control service delivery, or JCAHO's responsibility to continuously improve the safety and quality of care provided in hospitals, it is clear that there are a number of ways that the public's interest in competent providers will be addressed.

We recognize that the Agency's call for comments on provider competency will no doubt elicit comments from a number of stakeholders with varying perspectives. It seems likely that there will be a lack of complete consensus on the specifics (e.g. number of previous procedures performed, etc.) surrounding what makes a physician competent to provide this procedure. We encourage the Agency to not let this lack of complete consensus serve as a stimulant to the need for regulation in this area.

Boston Scientific realizes the need for specialized training for this procedure and has committed to a comprehensive training program. In essence, we believe it is important that we do all we can to provide a fund of knowledge to physicians and staff so that they can be credentialed. Toward this end, we will build on our long-standing and extensive PVD training courses. We will do this with courses on correctly diagnosing peripheral and carotid cases, making appropriate patient selection decisions, engaging in simulation training, and learning how to use our specific devices.

Efficacy of Embolic Protection Devices

Boston Scientific utilized an embolic protection device in its trials. A copy of slides providing an early overview of the 30-day pivotal safety data is attached for the Agency's consideration of the role of embolic protection devices.

The fact that AMA has created a CPT code to describe a CAS procedure with embolic protection, and that CMS initiated a request for (and soon will be making effective) a unique ICD-9-CM procedure code to capture CAS with embolic protection, would seem to indicate that a host of stakeholders believe that embolic protection will play an important role in the provision of CAS. Boston Scientific is of this opinion as well.

Results from Other Carotid Stenting Trials with High Risk Population

As the Agency may be aware, Boston Scientific has completed enrollment of our "BEACH" CAS clinical trial. As mentioned above, we have enclosed an early overview of our 30-day pivotal data. We are currently estimating that the analysis of our 1-year BEACH IDE clinical data will be available in April of 2005 when it is submitted to the FDA.

Evidence of the Efficacy and Appropriateness of Carotid Stenting for this Target Population

Based on the presentations related to CAS clinical trial status and data that have been made at various scientific meetings and our discussions with clinicians it appears that this technology is beginning to demonstrate its efficacy and appropriateness for the type of patients on whom it has been performed.

Over the last several years, peer-reviewed journals have looked at distinct target populations and the benefit of CAS over CEA with embolic protection. Enclosed are several of the peer-reviewed published articles with references and summary of endpoints.

(See Attachment A).

Degree of Facility Experience Requirements

As mentioned above, Boston Scientific believes it is important that the Agency recognize the overall effectiveness that established entities and procedures have played in ensuring that hospitals have the necessary experience to competently provide care. In addition, the Agency has its own standing methods of approving hospitals. While CAS is a significant procedure, these established entities and procedures will protect the public health. By relying on the existing mechanisms, the Agency will help to ensure that beneficiaries have timely, geographically reasonable and appropriate access to this procedure.

We would also suggest that the Agency utilize the February 3, 2004 letter to Dr. Sean Tunis from nine different specialty societies on the dimensions of specialty collaboration that will be necessary to ensure that facilities have the appropriate set of clinical resources in place. Assuming that this complement is in place, CMS should allow this service to be provided on an inpatient basis in any Medicare-approved hospital.

Types of Provider Training Programs to be Developed

First, manufacturers, specialty societies and clinical centers are engaging each other in many ways to ensure that health professionals are in a position to become competent to carrying out this procedure. Reinforcing this activity is the fact that any manufacturer of stents or embolic protection devices that are going to be used in conjunction with a carotid procedure will need to gain FDA acceptance of their educational plan. In addition, specialty societies and various clinical centers will be developing and implementing training programs.

To reiterate our earlier comment, Boston Scientific is committed to providing comprehensive and substantive educational programs that will provide physicians and staff with a knowledge bank to draw on to appropriately select patients and the safe use of the stent, embolic protection and appropriate accessories we will sell to treat carotid arteries. In addition, given the interest in the health professional community, we would expect that various societies and centers of care would pursue relevant training programs as well. Some of our training is already underway, while we expect other elements to be implemented in 2005.

Supporting Staff Required for the Procedure

Assuming that a hospital has the inter-disciplinary team (called for in the multi-society letter) in place, we believe that the staff that is commonly found in an inpatient hospital suite will be adequate for the provision of this service.

Specialty Requirements for the Procedure

Boston Scientific does not believe that this procedure should be limited to a specific specialty. Again, we encourage the Agency to look at the multi-society recommendations on inter-specialty consultation to determine appropriate patient selection for this procedure.

Stipulations to Ensure the Appropriate Use of the Procedure in the Indicated Patient Population

Appropriate patient selection will be achieved by the patient inclusion criteria the Agency will be describing in its coverage regulation. In addition, given the cross-specialty collaboration that is likely to be present around the determination of the appropriateness of this procedure, we encourage the Agency to stay with its practice of not requiring some sort of prior authorization.

We appreciate the opportunity to provide comment on this important coverage decision. Please contact me (763-494-2016; tom.meskan@bsci.com) if you have questions or need additional information. We look forward to working with CMS and others to achieve beneficiary access to this procedure.

Sincerely,

A handwritten signature in black ink that reads "Thomas L. Meskan". The signature is written in a cursive style with a large, stylized "M" and "L".

Thomas L. Meskan
Director of Reimbursement and Outcomes
Boston Scientific Corporation

Attachment A

1. Katzen BT, Laird JH, Ohki T, The SAPHIRE and ARCHeR Updates. *Endovascular Today*. 2003;Sept.:77-80.
2. Ramazanali A, Schillinger M, Lang W, et. al. Carotid Artery Stenting in Older Patients: Is Age a Risk Factor for Poor Outcome? *J.Endovascular Therapy*. 2002;9:559-565.
3. Brooks WH, McClure R, Jones MR, et al. Carotid Angioplasty and Stenting Versus Carotid Endarterectomy: Randomized Trial in a Community Hospital. *Journal of the American College of Cardiology*. 2001;38:6:1589-1595.
4. Brajesh KL, Hobson RW, Goldstein J, et. al. In-stent recurrent stenosis after carotid artery stenting: Life table analysis and clinical relevance. *Journal of Vascular Surgery*. 2003; 38:6:1162-1168.
5. Hobson RW, Brajesh KL, Chaktoura E, et. al. Carotid artery stenting: Analysis of data 105 patients at high risk. *Journal of Vascular Surgery*. 2003; 37:6: 1234-1239.
6. Cho JS, Pandurangi K, Conrad MF, et. al. Safety and durability of redo carotid operation: An 11-year experience. *Journal of Vascular Surgery*. 2004; 39:1:155-160.
7. Kastrop A, Groschel K, Krapf H, et. al. Early Outcome of Carotid Angioplasty and Stenting With and Without Cerebral Protection Devices. *Stroke*. 2003;34:813-819.
8. Dangas G, Laird JR, Mehran R, et. al. Carotid Artery Stenting in Patients With High Risk Anatomy for Carotid Endarterectomy. *J.Endovascular Ther*. 2001;8:39-43.
9. Angelini A, Reimers B, Barbera M, et. al. Cerebral Protection During Carotid Artery Stenting Collection and Histopathologic Analysis of Embolized Debris. *Stroke*. 2002;33: 456-461.
10. Al-Mubarak N, Colombo A, Gaines P, et. al. Multicenter Evaluation of Carotid Artery Stenting With A Filter Protection System. *Journal of the American College of Cardiology*. 2002; 39:841-846.
11. Houdart E, Mounayer C, Chapot R, et. al. Carotid Stenting for Radiation-Induced Stenosis A report of 7 cases. *Stroke*. 2002; 32:118-121.



EPISCOPAL
HOSPITAL

Dr. Joe Chin, MD
And Dr. Carlos Cano, MD
Lead Medical Officers
Medicare Coverage

July 13, 2004

RE: Coverage Request-Carotid stenting with protection in patients at high risk for endarterectomy.

Dear Dr's.

Like other large peer-reviewed medical centers, St. Luke's Episcopal Hospital and the Texas Heart Institute have extensive experience with embolic protection during angioplasty and stenting of the carotid arteries in patients at high risk for endarterectomy. Over 350 IRB approved high-risk carotid artery stent procedures have been performed at our institution. We strictly adhere to eligibility criteria when enrolling patients into a carotid stent protocol and closely follow them with routine duplex ultrasound and neurological exams. A multi-disciplinary team consisting of an independent neurologist, radiologist, interventional cardiologist and a vascular surgeon are consulted for each potential carotid stent candidate. Patients undergo a complete and thorough neurological examination before and after carotid stenting and must have 4-vessel cerebral angiography prior to carotid stenting.

Patients are considered at high-risk for endarterectomy if they have multiple comorbidities including symptomatic coronary artery disease, severe left ventricular dysfunction, chronic obstructive lung disease or those who have obstructions surgically inaccessible. Of the 350 carotid stent procedures performed at St. Luke's, 45% did not meet NASCET inclusion criteria, 19% were octogenarians, 28% had already undergone previous carotid endarterectomy and 13% had neck radiation and/or radical neck surgery to treat their cancer.

Currently at our institution only Principle Investigators and Co- Investigators of IRB approved clinical trials can perform carotid artery stenting. All of the investigators have extensive experience with peripheral and cerebral anatomy, arteriography and intervention, as well as, the use of distal embolic protection devices. All carotid stent procedures are monitored and followed by a designated peripheral vascular research coordinator.

A preceptor training program has been implemented at St. Luke's and coordinated by the carotid stent investigators. Those physicians wishing to obtain carotid stent privileges must adhere to the multi-disciplinary approach, including the neurological evaluation before and after the procedure. In addition each physician must satisfactorily perform 10 computer-simulated procedures, participate in 25 carotid stent procedures and perform an additional 10 proctored carotid stent procedures. All of the cases are subject to peer review.

Texas Medical Center

PO Box 20269

Houston, Texas 77225-0269

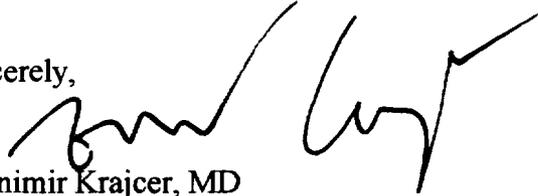
www.slch.com

An affiliate of St. Luke's Episcopal Health System

We would like to urge CMS to extend coverage beyond clinical trials to allow those patients at high risk for endarterectomy to undergo carotid artery stenting with protection.

If you have any further questions or comments or if we may be of further assistance please do not hesitate to contact us directly.

Sincerely,



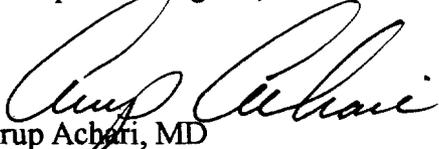
Zvonimir Krajcer, MD
Clinical Professor of Medicine
Baylor College of Medicine
The University of Texas Health Science Center
Principle Investigator, MAVERIC II



Ali Montazavi, MD
Director, Interventional Cardiology
Kelsey-Seybold Clinic
Principal Investigator, BEACH



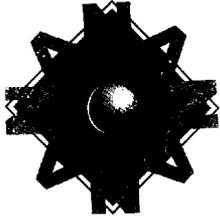
Neil Strickman, MD
Interventional Cardiologist
St. Luke's Episcopal Hospital
Principal Investigator, SAPPHERE



Arup Achari, MD
Interventional Cardiologist
St. Luke's Episcopal Hospital
Co-investigator, SAPPHERE



Emerson Perin, MD
Interventional Cardiologist
St. Luke's Episcopal Hospital
Co-investigator, SAPPHERE



NEUROSURGICAL ASSOCIATES, PSC

1401 Harrodsburg Road

S u i t e B 4 8 5

Lexington, Kentucky 40504

859-277-6143 Fax 859-277-8659

William H. Brooks, M.D.

James R. Bean, M.D.

Steven P. Kiefer, M.D.

Brett A. Scott, M.D.

Harold Mazurek, PA-C

Debbie Croucher, PA-C

Julie L. Tudor, PA-C

Vicki P Turnbull, CMPE, CPC
Practice Administrator

TO: The Centers for Medicare and Medicaid Services (CMS)

1. Dr. Joe Chin
2. Dr. Carlos Cano
3. Rana Hogarth, MSH

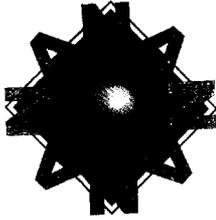
FROM: William H. Brooks, M.D. *WBrooks*

RE: Carotid Stenting Coverage Policy (CAG – 00085R)

I welcome an opportunity to comment and present my conditional support, yet significant and serious concerns regarding a proposed approval of reimbursement for carotid angioplasty and stenting (CAS). The issues surrounding CAS are numerous and require careful consideration before providing reimbursements to providers, in my opinion. How this can be clearly and reasonably addressed is anything but clear. Local credentialing committees are plagued by politics and “turf-wars”. No consensus regarding proper training of those physicians already in practice has been reached by various societies. The indications for treating asymptomatic carotid disease are not without controversy. In addition, the definition for “high risk” remains opaque. In short, there is no bench mark.

The comments to follow represent my personal thoughts based on my collective experience with CAS. Enclosed find copies of two randomized trials completed in a single community hospital setting comparing carotid endarterectomy (CEA) and CAS. Initially, I was engaged in the Schneider Wallstent trial and was a Principle Investigator on ARChER and BEACH registries. These were industry sponsored registries for “high risk” patients. The data from these registries have been presented/published. Unfortunately, the data from the Wallstent trial never will be published. Nevertheless, the information gathered from that trial provides clear insight into the potential problems associated with CAS and the general community where this procedure is not routinely performed and experience required to acquire the sufficient skills to safely be engaged in CAS are suspect and often lacking.

It is clear the request for changes in funding practices that currently exist as developed by CMS is industry driven. Contacts from industry requesting providers to lobby CMS for change of funding have been received. Obviously, providers wish to have appropriate reimbursement for the services that are delivered. Nevertheless, this particular challenge has been led by industry. Why? To expand a market share and wealth, no doubt. Why else would



NEUROSURGICAL ASSOCIATES, PSC

Page Two

1401 Harrodsburg Road

S u i t e B 4 8 5

Lexington, Kentucky 40504

859-277-6143 Fax 859-277-8659

William H. Brooks, M.D.

James R. Bean, M.D.

Steven P. Kiefer, M.D.

Brett A. Scott, M.D.

Harold Mazurek, PA-C

Debbie Croucher, PA-C

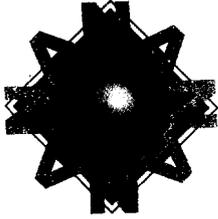
Julie L. Tudor, PA-C

Vicki P Turnbull, CMPE, CPC
Practice Administrator

industry send information that states “or, it might craft overly restrictive coverage regulations on the patients to be served, physician competency, or facility experience. This could severely limit physician and patient access to this service”. It is my view that it is these restrictive coverage’s that lie at the heart of considering reimbursement. My intention is not to present a dissenting message, rather one that expresses the concerns as experienced in the community hospital setting with hopes to offer an approach that might have been overlooked given the politics of the technique and the various providers that will be or wish to be engaged.

As a preamble to further explication of my position, review the Asymptomatic Carotid Artery Stenosis trial (ACAS) and the information gathered from the Schneider Wallstent Trial. The ACAS Trial demonstrated the benefits of CEA, in asymptomatic individuals with stenosis of 60% or greater, if and only if, the individual was anticipated to live more than five years and a provider morbidity and mortality was less than 3%. Actually, the surgeons involved in this trial were carefully selected with a surgical risk significantly less than 3%. Once this study was published those engaged in CEA proscribed surgery for individuals with carotid stenosis such that the numbers of CEAs increased by 10 fold within one year. Subsequent data gathered by the Federal Government revealed the surgical risks, morbidity and mortality, were far in excess of those proscribed by ACAS guidelines. Still, the practice continues without constraint. The literature is replete with articles and opinions condemning the blatant overuse of CEA in asymptomatic individuals. Nevertheless, CEA is beneficial in an appropriate clinical setting with an acceptable surgical risk. CMS must be aware that similar to the consequences of release of the ACAS trial, the numbers of CAS will dramatically increase with a potential for a marked increase in rates of complications and abuse.

The Schneider Wallstent Trial was discontinued because the complications associated with CAS were far in excess of those associated with CEA. One of the reasons for the failure of this trial was that there were little, if any, selection criteria for those to become engaged in CAS. Subsequently, it has been suggested that an individual must perform 50 – 100 CAS to become thoroughly qualified and trained. Clearly, the numbers wishing to adopt this technique far exceed those actively engaged at this time.



NEUROSURGICAL ASSOCIATES, PSC

Page Three

1401 Harrodsburg Road

S u i t e B 4 8 5

Lexington, Kentucky 40504

859-277-6143 Fax 859-277-8659

William H. Brooks, M.D.

James R. Bean, M.D.

Steven P. Kiefer, M.D.

Brett A. Scott, M.D.

Harold Mazurek, PA-C

Debbie Croucher, PA-C

Julie L. Tudor, PA-C

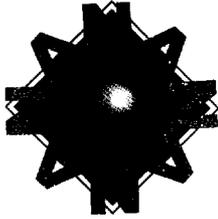
Vicki P Turnbull, CMPE, CPC
Practice Administrator

The trials on which industry has based the argument that CAS warrants funding approval is based on "high risk" registries. Presently, there are no randomized trials comparing CEA with CAS that have been published other than those from our community hospital. Although these trials show that CEA and CAS may be equivalent, this data is obtained in only one clinical setting where a team approach was utilized. This cannot and should not be taken as a definitive study. CREST will serve as a definitive study similar to what NASCET did for endarterectomy and symptomatic disease. The definition for "high risk" is clearly in the eyes of the surgeon. Personally, I believe there is a small group of individuals who actually are placed at increased risk for carotid revascularization by "open surgery". Most, if not all, surgeons and those engaged in CAS would include:

1. Severe pulmonary insufficiency and/or cardiac disease with reduced ejection fraction;
2. Previous irradiation of the neck;
3. Surgically difficult access to the area of interest such as high bifurcation of the common carotid artery; and
4. Previous CEA.

These are similar to those proscribed and detailed in high risk trials that have been published or presented. This group of patients, however, represents the vast minority of those presenting with carotid stenosis. Most reports of CAS in the literature contain large numbers of asymptomatic individuals.

Provider qualification and training also is a key issue that must be carefully considered before funding. The "learning curve" for safely performing CAS has been suggested to be between 50 – 100 cases. Those physicians best prepared to adopt this technique at present seem to be cardiology and radiology "interventionalist" or those with catheter based skills. Providers without these skills are poorly prepared for CAS. Additionally, those without experience in manipulation of small (0.014m) guide wires are poorly prepared. Thorough knowledge of cerebrovascular anatomy and management of stroke is mandatory. To be partially competent equals partially incompetent. Although competition for these patients will be fierce among the various disciplines, it is doubtful that the numbers of providers wishing to become involved with CAS, at present, are trained appropriately. Clearly the numbers wishing to adopt this technique far exceeds those actively engaged at this time. Academic training programs are providing experience with CAS that will serve the needs of the public in an



NEUROSURGICAL ASSOCIATES, PSC

Page Four

1401 Harrodsburg Road

S u i t e B 4 8 5

Lexington, Kentucky 40504

859-277-6143 Fax 859-277-8659

William H. Brooks, M.D.

James R. Bean, M.D.

Steven P. Kiefer, M.D.

Brett A. Scott, M.D.

Harold Mazurek, PA-C

Debbie Croucher PA-C

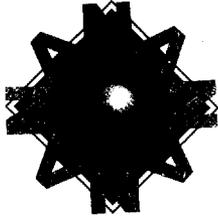
Julie L. Tudor, PA-C

Vicki P Turnbull, CMPE, CPC
Practice Administrator

appropriate fashion in the near future. Yet the problem is current and the issues of proper qualifications to perform CAS in the interim need to be addressed. I am unaware of any guideline that generally would be acceptable without reserve and dissent. CORDIS manufacturer has proposed a training profile that seems reasonable. Certainly, this is a place from which to start. The stratification of providers provides for immediate approval as well as a proscription for training and proctoring. Strict monitoring of outcome, however, is lacking. It is my understanding that carotid stents will be provided only to those physicians who have met the criteria of CORDIS. Such an approach seems reasonable as long as outcomes are measured in context of appropriateness and acceptable morbidity and mortality as compared to CEA. I might suggest that you look at there criteria. It is not perfect, but at least an attempt and may be relevant until adequate numbers of academically trained provides enter the market. Nevertheless, the issues of local credentialing remain local and problematic. CMS funding will only add to that problem unless federally mandated constraints are in place.

Industry has expressed concern that CMS may propose “overly restrictive covered regulations” based on facility experience. Personally, I welcome such an approach. Those facilities that offer CAS must also offer acute stroke intervention. Anyone engaged in CAS must be prepared to suddenly become responsible for stroke therapy. Those of us engaged in CAS keenly are aware of the potential for a therapeutic endeavor to become a procedure of rescue. Thus, CAS cannot separate prevention from stroke therapy. Therefore, a facility without a documented acute stroke interventional protocol in place and functioning is an inappropriate setting for CAS. The guidelines for accreditation must be set higher than perhaps all can attain less the complication rates associated with CAS become unacceptable in comparison to CEA. This is an evolving technique with great potential, yet I fear, the technique may be discarded unless the early introduction to healthcare services is strictly controlled until sufficient data is obtained to warrant unrestricted use.

The use of embolic protection devices is an example of the evolution of this technique. The trials that I have presented did not use embolic protection devices as they were not available. Those of us involved in CAS as a protective measure, however, have adopted the use of these devices. However, the embolic protection device is not a safeguard against misuse, abuse, and a lack of appropriate training.



NEUROSURGICAL ASSOCIATES, PSC

Page Five

1401 Harrodsburg Road

S u i t e B 4 8 5

Lexington, Kentucky 40504

859-277-6143 Fax 859-277-8659

William H. Brooks, M.D.

James R. Bean, M.D.

Steven P. Kiefer, M.D.

Brett A. Scott, M.D.

Harold Mazurek, PA-C

Debbie Croucher PA-C

Julie L. Tudor, PA-C

Vicki P Turnbull, CMPE, CPC
Practice Administrator

The most difficult problem that CMA faces (not that those mentioned above are not problematic) is to insure appropriate patient selection by providers once CAS is funded. Personally, I do not believe that there is any methodology that would serve this function other than regionalization of services and strict federal oversight. The history of medicine is replete with examples of appropriate use and abuse of surgical procedures by healthcare providers. The consequences of ACAS trial are merely one example that may be applicable and serve as a warning of that potential with CAS.

In summation, one option, although obviously not palatable to industry, is to defer full funding until the results of CREST have been obtained. I would suggest that CMS approve and fund high risk registries sponsored by industry and provide coverage only in the context of these registries or randomized, prospective trials. Reimbursement for CAS in the context of randomized, prospective trials does not need to be confined to those sponsored by industry, but also may include those sponsored in a local academic or community hospital setting. The trials that we conducted were unfunded and no reimbursement either for the hospital or physician services was received or expected. This is by far the better route, in my opinion, than releasing CAS to any physician holding the belief that because he is a surgeon with CEA experience, radiologist with the belief that all endovascular procedures are similar, and the cardiologist suggesting the coronary skills translate to knowledge of cerebrovascular anatomy and indications for cerebral re-vascularization.

Thanks for your time, I generally do not become engaged in these debates, but the potential for abuse is so high I was obliged.