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March 2, 2007

Steve Phurrough, MD, MPA
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RE: Comments on the Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)

Dear Dr. Phurrough:

Abbott appreciates the opportunity to comment on the Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting.

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries. Abbott is a leader in carotid stenting and related clinical research, with nearly 10,000 high surgical risk patients participating in Abbott's studies. Two of Abbott's trials, CREST and ACT are randomized clinical trials of CEA vs. CAS, designed to understand the benefits of carotid stenting in normal risk patients. While this patient population is not directly relevant to this coverage decision, Abbott is the only company studying this population in such detail and is committed to developing rigorous evidence on the outcomes of CAS across various patient populations.

Abbott applauds CMS for expanding coverage to asymptomatic patients under age 80 with ≥ 80% stenosis. Abbott agrees that sufficient evidence exists, specifically from multiple FDA approval studies, followed by confirmation from post approval studies including CAPTURE, to expand coverage to this important patient group that previously did not have access to CAS.

Abbott would like to provide comments on the following provisions of the draft decision:

1. The restriction of all high risk octogenarians, regardless of symptomatic status, to coverage only when in enrolled in a Category B IDE clinical trial or post-market study.
2. The proposed facility certification and recertification process, SCAI-CAP,
3. The requirement that the surgical consult to determine a patient's high risk status be performed by a surgeon properly credentialed to perform CEA as determined by the facility, and
4. The proposal not to expand coverage for patients at high risk for CEA who have symptomatic carotid artery stenosis between 50-69%.

1. Coverage of High Risk Octogenarians

Abbott agrees that additional data is necessary to better understand outcomes in the octogenarian population. Abbott believes that outcomes in octogenarians are potentially a result of an underlying condition (i.e. challenging anatomy, decreased cerebral reserve, etc.) as opposed to age, and is rethinking its post market study strategy to ensure we address the learning needed in this population.

2. Facility Certification Proposal

In general Abbott supports a rigorous accreditation and recertification program, whether it is CMS or society based. Abbott believes an ideal program would integrate the CMS system with other "approved" systems for collection of data (i.e. society databases or such), be minimally burdensome on the hospital and at a reasonable cost, be managed by an entity knowledgeable of requirements of the CAS procedure, use data collected to enable recertification, and importantly, mandate that facilities have a process and audit mechanism in place to determine a patient's high surgical risk status.

CMS specifically requested comments on the SCAI-CAP proposal, and Abbott believes that the proposal does appear to be rigorous and generally meets the criteria listed above. Abbott would welcome an opportunity to comment on a multi-society proposal as well, should one be put forward.

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3. Surgical Consult

In the proposed coverage decision, CMS has included a provision that requires that the surgical consult to determine a patient's high risk status be performed by a surgeon "properly credentialed to perform CEA as determined by the facility." Abbott believes that CMS' concern is that a broader population of patients is being treated than only those at high risk for surgery. Abbott continues to believe that clinical studies have clearly and objectively defined high surgical risk criteria and therefore the surgical consult simply introduces subjectivity into an objective process, and that there is a more objective way to ensure the proper patients are being treated with CAS.

<u>High risk criteria that are clear, objective and verifiable</u>

Abbott believes that the high risk criteria CMS has listed in the proposed coverage decision are well defined and when compared against CAS studies, are reflective of that which was reviewed by the FDA. It does appear that two lists of high risk criteria are part of the proposed decision, one abbreviated list in the general text, and one expansive list of data elements required for recertification. Abbott recommends that the data elements portion be reflective of the inclusion criteria used in high surgical risk carotid stenting IDE studies. Following is a table with an expanded list of high risk criteria, the basis of which is CMS' data element list, along with the supporting IDE studies that included the criteria. The table below includes any high risk criteria that were in 3 or more of the IDE studies, and as such is slightly different than the CMS data element proposal. Additions and modifications are noted in the table, and only one element was removed, abnormal stress test. While this element was listed as a high risk criteria in two of the studies, it did not meet the "at least three study" cutoff. Upon review of this list, it is apparent that certain of these high risk criteria, in particular end stage renal disease, COPD, and NYHA Class III/IV heart failure, are best evaluated by medical professionals other than a surgeon.

Table 1: High Surgical Risk Criteria: CMS and IDE Studies
ARCHER [1], BEACH[2], CREATE[3], CABERNET[4], SAPPHIRE[5,6], SECURITY[7]

Modified/Expanded Proposed CMS High Risk Criteria	High Surgical Risk IDE Studies with this or similar Criteria
Specific Conditions	
Contralateral laryngeal nerve palsy, injury, or paralysis† ***(each trial had a variation of this criteria)***	**ARCHER, BEACH, CABERNET, CREATE, SAPPHIRE, SECURITY**
Tracheostomy or Tracheal stoma†	**ARCHER, BEACH, CABERNET, CREATE,**

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	SECURITY
Restenosis of prior carotid endarterectomy (CEA)	**ARCHER, BEACH, CABERNET, CREATE, SAPPHIRE, SECURITY**
Previous radical neck dissection or surgery*	**ARCHER, BEACH, CABERNET, CREATE, SECURITY**
Previous Radiation therapy to neck or head†	**ARCHER, BEACH, CABERNET, CREATE, SAPPHIRE, SECURITY**
Spinal Immobility*	**ARCHER, BEACH, CREATE CABERNET, SECURITY**
High cervical internal carotid artery lesions/common carotid artery lesions below clavicle ***(each trial had a variation of these criteria)***	**ARCHER, BEACH, CABERNET, CREATE, SAPPHIRE, SECURITY**
Severe tandem lesions*	**CREATE (≥ 70% stenosis), SAPPHIRE, SECURITY**
Age > 80	**BEACH (age ≥ 75 y), CABERNET (age ≥ 75 y), CREATE (age ≥ 75 y), SAPPHIRE, SECURITY**
Contralateral carotid occlusion	**ARCHER, CABERNET, CREATE, BEACH, SAPPHIRE, SECURITY**
Severe Vascular/Cardiac/Other Comorbidities	
Congestive heart failure (New York Heart Association class III/IV)	**ARCHER, BEACH, CABERNET, CREATE, SAPPHIRE, SECURITY**
Known left ventricular dysfunction (LVEF <30%)	**ARCHER, BEACH, CABERNET, CREATE (<35%), SAPPHIRE, SECURITY (<35%)**
Open heart surgery (within 6 weeks) †	**ARCHER (within 30 days)** **BEACH (planned open heart or other major surgery post procedure)** **CABERNET (includes peripheral vascular surgery, no time frame given, staged procedure)** **SAPPHIRE (within 6 weeks)** **SECURITY (including peripheral vascular surgery or AAA repair within 60 days)**
Recent myocardial infarction (30 days) †	**ARCHER (30 days), BEACH (≥24hr, ≤ 30 days), CABERNET (6 weeks), CREATE (>72 hours and < 6 weeks), SAPPHIRE (>24hr, <4 weeks), SECURITY (6 weeks)**
Two vessels with coronary artery disease ≥ 70%*	**ARCHER, BEACH, CABERNET, CREATE**
Unstable angina (Canadian Cardiovascular Society class III/IV)	**ARCHER, BEACH, CABERNET, CREATE, SAPPHIRE, SECURITY**
Severe pulmonary disease	**ARCHER (FEV1 < 30%), BEACH (FEV1 ≤ 30%), CABERNET (FEV1 < 50%), CREATE (FEV1 < 50%), SECURITY (FEV1 <50%), SAPPHIRE (FEV1 ≤ 50%)**
Renal failure: end stage renal disease on dialysis	**ARCHER, CABERNET, SECURITY**

* Not in CMS data element list
† Modified from CMS data element list

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EVA-3S[8] and SPACE[9] are normal risk studies

CMS cites concern arising from EVA-3S and SPACE as its rationale for the surgical consult. It is important to note that both of these studies are of normal risk symptomatic patients, and are therefore not relevant to this coverage decision. Further, it is important to note that while often grouped together as having similar outcomes, EVA-3S and SPACE are distinctly different and show quite different results.

SPACE is a German randomized clinical trial of CEA vs. CAS conducted in normal surgical risk symptomatic patients. The study was halted due to insufficient funding, and the interim results published despite the fact that it was terminated prior to full enrollment (1200 patients randomized vs. the initial planned 1900 patients randomized). The reported trial results for the primary endpoint of death or ipsilateral ischemic stroke at 30 days post procedure were 6.84% for CAS and 6.34% for CEA, *with no statistically significant difference in 30 day outcomes between the two therapies*.

EVA-3S is a French randomized clinical trial of CEA and CAS in normal risk symptomatic patients. The CAS outcomes were significantly worse than the CEA outcomes, but are the subject of much debate as a close review of the trial reveals many shortcomings in trial design and methodology.

Of major concern with EVA-3S is use of dated technique and standard of care, specifically low early use of EPD, a high number of cases where pre-dilatation was not used, a high number of cases (~30%) which used more than local anesthesia, and the failure of the protocol to mandate dual antiplatelet therapy.

Beyond the issues of standard of care in EVA-3S was the limited investigator experience in the CAS arm. Operators were allowed to participate in the trial if they had performed a minimum of 12 lifetime CAS procedures, or a minimum of as few as 5 CAS procedures if they had performed 35 supra-aortic procedures. Further, operators with no CAS experience were allowed to be proctored in the study. Clearly operator experience was substantially below that of CREST and ACT, and also below established US and EU standards.

In summary, Abbott believes that not only are these trials of a different patient population not the subject of this coverage decision, but each trial has significant limitations and results need to be interpreted cautiously.

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Impact to the patient and the system

Abbott believes that the proposed surgical consult will unnecessarily burden the system and could negatively impact the patient and potentially cause adverse outcomes. The surgical consult will have additional costs associated with it and represents a tremendous workload increase, which could slow down time-to-treatment considerably. The patient is therefore being placed in a vulnerable position, with the delays in treatment time likely to result in unnecessary strokes.

Abbott proposes a different approach to ensuring a patient's high risk status

Abbott proposes that the facility certification and recertification process mandate, as a condition of certification, that a facility have a process in place to determine if patients are at high risk for CEA and to audit compliance with the requirement that Medicare coverage be limited to high risk patients.

Abbott proposes that as a condition of re-certification, the facility must demonstrate that the process has been followed, and any necessary corrective actions have taken place.

4. Symptomatic patients with stenosis between 50-69%

CMS proposes that symptomatic patients with stenosis between 50-69% only be covered in Category B IDE clinical trials or post market studies. CMS bases this proposal primarily on the recently published European trials EVA-3S and SPACE, stating that the results do not provide sufficient evidence to expand coverage and specifically stating that because results are not presented by degree of stenosis severity, it is not possible to determine whether this population experienced better or worse outcomes.

Abbott believes for several reasons that this patient population should be covered. With regard to EVA-3S and SPACE, for reasons previously stated, Abbott believes that those trials are not relevant for this coverage discussion.

As the result of Medicare coverage restrictions, Medicare patients who are symptomatic with stenosis 50-69% and at high surgical risk have limited access to CAS. At the same time these same patients are commonly being treated with CEA, when evidence exists to suggest that this may not be the best course of treatment.

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The evidence on this population with 50-69% stenosis, when examining Abbott's extensive post market study experience, demonstrates that the results are favorable. Pursuant to data shown in Abbott's meeting with CMS on February 23, 2007, 30 day stroke/death outcomes are comparable to NASCET, but in a high surgical risk patient population and in a 'real world' study.

Summary

In summary, Abbott applauds CMS' decision to expand coverage to asymptomatic patients under the age of 80. However, we propose the following changes to the NCD:

1) Surgical Consult
   Mandate that as a condition of facility certification, a high risk status determination process be in place, and an audit process post procedure. Mandate that as a condition of re-certification, the facility must demonstrate that the process has been followed, and any necessary corrective actions have taken place.

2) High risk criteria
   Ensure that high risk criteria requested as data elements be reflective of high risk IDE study inclusion criteria.

3) Symptomatic patients with stenosis between 50-69%
   Expand coverage to high risk symptomatic patients <80 years with stenosis between 50-69%.

Abbott appreciates the opportunity to comment on the proposed coverage of CAS. We look forward to continuing to work with CMS to assure appropriate access to CAS for Medicare beneficiaries.

Sincerely,

Barbara J. Calvert

Barbara J. Calvert
Director, Medical Products Reimbursement

cc Sarah McClain, MHS
Marcel Salive, MD, MPH

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Virginia Tobiason, Sr. Director, Corporate Reimbursement
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March 3, 2007

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Re: Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)

Dear Ms. McClain and Dr. Chin:

The American College of Cardiology appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed National Coverage Decision (NCD) Memo on Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3). The ACC is a 34,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy.

With regard to the proposed NCD memo, the ACC commends CMS for approving the CARE Registry™ as a vehicle for the data collection required for facility certification and recertification for performing carotid artery stenting (CAS). We support CMS's emphasis on regular data collection and analysis as a way to continuously improve the care provided to Medicare and other patients receiving CAS procedures, and are encouraged that CMS is willing to revisit this issue and re-assess the evidence-base upon which the safety and efficacy of carotid artery stent (CAS) and carotid endarterectomy (CEA) can be evaluated.

We remain seriously concerned however, that four specific changes identified in the proposed NCD will not result in improved patient care, and worse, may contribute to patient harm. Following are our specific comments on each of these four areas.

1. Restrict the current coverage for patients who are at high risk for carotid endarterectomy (CEA) and have symptomatic carotid artery stenosis > 70% to patients who are less than 80 years of age:

The ACC opposes this restriction of coverage for CAS for patients less than 80 years old as it appears to set an arbitrary standard that is unsupported by current literature. In fact, we believe the indication for the treatment of symptomatic patients with CAS should be extended to lesions with stenosis severity of ≥ 50% and ≤ 99% irrespective of age for several reasons, the most important of which is to allow trained and qualified physicians to determine with the patient what the best course of treatment is to pursue. This change in Medicare coverage policy for CAS may have the adverse effect of harming patients over 80 years of age who, but for their age, would otherwise be appropriate candidates for, and would likely benefit significantly from, CAS.

There is overwhelming (Level I) evidence that symptomatic patients with stenosis severity of ≥ 50% and ≤ 99% carotid stenosis benefit from revascularization (carotid endarterectomy) compared to "best" medical therapy. ***1,2,3*** This is standard everyday practice in the US and around the world. There are expert consensus documents that support this strategy. Despite concerns regarding the upper boundary for the 30-day complication rate (≤ 6% stroke or death), there is still evidence that such treatment results in patient benefits. ***4*** While there is debate about what constitutes "best" medical practice, that issue deserves further study. Regardless, adjuvant medical therapies have not replaced revascularization as primary therapy for these symptomatic patients with significant carotid stenosis.

In analyzing this data, it is critical to differentiate "symptomatic" vs. "asymptomatic" and "high surgical risk" vs. "non-high risk" groups, as their outcomes appear to be different. There is peer-reviewed evidence to support CAS with embolic protection as an alternative to CEA in "high surgical risk" (HSR) patients with symptomatic carotid stenosis ≥ 50% and ≤ 99%. This globally accepted supporting evidence for non-inferiority and perhaps superiority of CAS to CEA in high surgical risk patients is from a randomized prospective multi-center controlled trial (SAPPHIRE) ***5***, as well as multiple FDA approved, industry sponsored registry trials in "high surgical risk" patients with symptomatic carotid stenosis ≥ 50% and ≤ 99%. ***6-9***

Additionally, the ACC respectfully disagrees with CMS' conclusions as provided in the following statement, taken from Section VIII, CMS Analysis:

> "The EVA-3S and SPACE trials did not limit inclusion to only patients at high risk for CEA surgery. It is unclear what, if any, influence this had on the outcomes, but it would be reasonable to believe that patients at low risk would have better outcomes than patients at high risk. These trials do support the use of distal embolic protection devices and showed poor patient outcomes when they were not used. We required the use of distal embolic protection devices with CAS in our prior decision for the

safety and protection of patients and will continue this requirement. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection."

There is a fundamental flaw in this reasoning because CEA risk and CAS risk for complications are largely separate issues. Patients at low surgical risk will have better outcomes after CEA than high surgical risk, but this rationale does not hold for CAS. Patients with multiple comorbidities, i.e. heart disease, lung disease, and renal disease are likely to have more "events" over time than a healthy patient—but this does not necessarily translate into a lower 30-day stroke and death rate.

These conclusions are arguable, given that: 1) both trials excluded high-surgical risk patients and therefore these data are not applicable; and 2) there were serious problems with the conduct and perhaps "impartiality" of these trials. ***10-13*** SPACE was underpowered to reach its pre-specified endpoints, with the 30-day stroke and death rate for CAS = 6.8% and CEA = 6.3% (p = ns). ***10***

2. Expand coverage to patients who are at high risk for CEA and have asymptomatic carotid artery stenosis >80% and are less than 80 years old:

While the ACC supports this proposed expansion of coverage for beneficiaries under the age of 80, again, as with our concerns outlined in the previous section, we believe that restricting reimbursement for revascularization procedures in octogenarians is not justified by current data. While complication rates in the very elderly appear to be higher for both CEA and CAS, it is not clear that age is the primary risk factor for CAS-related complications. There is currently a debate in the literature suggesting that elderly patients can safely undergo CAS. ***15, 16*** Data from Setacci et al.***16*** suggest that difficult arch anatomy and a preponderance of calcified plaque in the arch vessels may predispose some elderly patients to complications. Additionally, if, in the opinion of an expert, an octogenarian requires carotid revascularization and is deemed to be at high-surgical risk for reasons other than age alone, withholding CAS prevents appropriate therapy for patients in need.

3. CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible:

The ACC categorically opposes this proposed clarification of the NCD policy, as it would impose untenable burdens and risks to both physicians and patients if adopted. While deployment of embolic protection devices in many cases may be appropriate or even desirable, it may not be in others. We do not see the benefit of denying effective therapy to a patient without an alternative who has a stenosis of such severity that an embolic protection device is unable to cross the lesion, but may still benefit greatly from undergoing CAS.

The proposed clarification, if adopted, introduces a number of unintended, significantly adverse consequences for patients and physicians, and raises serious issues that may not have been considered at the time this clarification was proposed. The ACC urges CMS to consider the following:

- The ability to convert a CAS patient to CEA requires that they be considered candidates for CEA in the first place. In the event a Medicare beneficiary is determined not to be a candidate for CEA prior to undergoing CAS, he/she is faced with the choice of whether to proceed with a potentially lifesaving procedure while also assuming the financial burden incurred, or risk further deterioration of their health by electing not to undergo CAS. The Medicare program should not force patients into having to make such false choices, especially where the condition being imposed by CMS (deployment of embolic protection as a condition of coverage) is not necessary for successful performance of the CAS procedure.

- The clarification also needlessly complicates the physician's responsibility for securing informed consent from patients prior to undertaking the CAS procedure. Specifically, the physician must explain to the patient the risk that failure to successfully deploy an embolic protection device during the operation transfers financial responsibility for the procedure from Medicare to the patient. Consequently, the physician must ensure that he/she obtains the patient's consent to either continue the operation in the event the embolic protection device cannot be deployed, or terminate the procedure if deployment was unsuccessful. The contemplation of making either choice defies ethical standards. This is especially so with the latter option since the physician would have to agree to the possibility of placing the patient at risk for no benefit if he/she had to abandon the CAS procedure according to the patient's predetermined wishes. From an administrative standpoint, this scenario raises the additional question of whether the physician may seek reimbursement from Medicare for "work performed," or if the patient is left financially responsible for a procedure that was not completed, and had placed him/her at risk without having achieved any medical benefit. Several variations of this hypothetical scenario may arise, such as:

    - A preoperative patient presents as a viable candidate for both CAS and CEA, but, in the course of performing the procedure the operating physician encounters unforeseen difficulties that prevent deployment of the embolic protection device. The physician must decide whether to continue the procedure—ideally he/she secured the patient's informed consent to proceed or terminate prior to beginning the procedure.

    - Where informed consent for the above scenario is not secured, the physician may feel pressure to try "harder" to make these devices cross lesions that are not amenable to passage with the device. This may lead to

excessive catheter manipulation, which increases embolic complications. Cao, et al.***14*** reported that 50% of the disabling strokes associated with CAS occurred before placement of cerebral protection device during cannulation of the supra-aortic vessels. For high-surgical risk patients, an *attempt* at using an embolic protection device should be the requirement for coverage/reimbursement.

- In the case of the physician who encountered unforeseen difficulties preventing deployment of the embolic protection device, he/she may be legally exposed to the patient's potential claims of malpractice—e.g. failure to meet the standard of care, etc.—or breach of contract for services due to the physician's failure to meet the NCD's coverage requirements, which may have been a pre-condition for undertaking the procedure.

4. Establish that the surgeon performing the surgical consultation that determines a patient's high risk status must be properly credentialed to perform CEA as determined by the facility:

The ACC also categorically opposes this requirement, as it needlessly adds complications to the diagnostic process, without any clearly demonstrable medical benefit supported by current literature. If there are no clear, evidence-based reasons to restrict state-licensed cardiologists from performing CAS on patients—as they have already been doing since conceiving this procedure from the outset—then this requirement unnecessarily delays and/or restricts patient access to this valuable treatment.

In addition, the studies cited by CMS in the proposed NCD memo as supporting this new requirement are problematic and inconclusive. For example, Rothwell et al. have raised concerns regarding self-reporting of data by surgical specialists, citing this as a plausible explanation for the variability of endpoints reported in surgeon-authored reports compared to reports authored by neurologists.***18*** The assessment of pre-operative co-morbid risk has traditionally been the purview of internal medicine, vascular medicine, and/or cardiology physicians. Other than SAPPHIRE, which required a consensus decision among the neurologist, surgeon, and interventionalist to perform CEA or CAS, none of the FDA sanctioned high-surgical risk pre-market CAS approval trials or post-market CAS surveillance trials have required "surgical permission" to enroll patients in the CAS arm. ***6-9*** Should CMS be concerned that non-high risk patients will undergo CAS outside of an FDA-approved clinical trial, alternative strategies to protect against this exist.

As stated earlier in these comments, the ACC supports and appreciates CMS' determination that facilities enrolled in CMS-approved national carotid artery stenting registries, such as NCDR-CARE™ will automatically meet data collection standards required for initial and continued facility certification.

Of interest to CMS might be that the CARE Registry™ is committed to promoting data harmonization among the stakeholders of the carotid artery stenting community, including CMS and the Food and Drug Administration (FDA). To that end, we are organizing a meeting of such stakeholders to explore using CAS registries as a mechanism for unifying or streamlining reporting of post-market surveillance data.

With regard to whether CMS should transfer responsibility for reformulation and conduct of CAS facility certification and recertification, the ACC supports the Society for Cardiovascular Angiography and Interventions' (SCAI) proposal to assume this role for CMS. The process outlined in the SCAI proposal is sound and represents the substantial field experience enjoyed by SCAI through their Cardiovascular Catheterization Laboratory Survey Program (SCAI Lab Survey Program), which has been actively reviewing the quality of care provided by these laboratories since 1981. The framework for SCAI's proposed Carotid Accreditation Program (CAP) reflects an emphasis on data collection and review for objective, evidence-based evaluation of facility qualifications for accreditation. This emphasis on using objective, measurable standards of quality, combined with appropriate on-site reviews will enable the SCAI CAP to succeed in accrediting only highly qualified facilities for treating Medicare beneficiaries.

Our recommendations on this coverage issue are based on our knowledge of the most relevant and current clinical literature available. Our goal is to assist CMS in making appropriate coverage decisions based on scientific evidence. The ultimate judgment regarding care of a particular patient must be made by the physician and patient in light of all of the circumstances presented by the patient. We advocate safe, effective therapy for our patients with carotid artery stenosis, and believe that physicians who are dedicated to the care of these patients are best suited to determine appropriateness of therapy. We would urge CMS to consider this factor when refining the coverage decision, and would be eager to work with CMS to insure appropriate care to our patients in need.

As we stated in our previous comment letter submitted during the initial comment period, the ACC does not view CAS as exclusive therapy for carotid stenosis. There are many clinical scenarios in which CEA or medical therapy might be appropriate, and there are centers that provide excellent surgical therapy for high risk patients. However, approval of CAS provides a reasonable and scientifically sound alternative in appropriate patients, when the procedure is performed by skilled interventionists in credentialed centers. This is a responsible approach to a population of patients with multiple co-morbidities and challenges, and is appropriate. In addition, post-marketing surveillance data will aid in demonstrating safety and efficacy of both treatments in community and academic institutions, providing reassurance to Federal government, physicians, and most importantly, our patients.

Again, the ACC appreciates the opportunity to comment on CMS' NCA on PTA of the Carotid Artery Concurrent with Stenting. We would be happy to work with you on any of our recommendations. If you have any questions, please contact Sergio A. Santiviago, Senior Specialist, Regulatory Affairs at [redacted], or by e-mail at [redacted].

Sincerely,

Steven E. Nissen, M.D. F.A.C.C.
President

Michael R. Jaff, DO, F.A.C.C.

Christopher J. White

Christopher J. White, M.D., F.A.C.C.

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March 2, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG-00085R3

Dear Sir/Madam:

On behalf of the American Stroke Association (ASA), a division of the American Heart Association (AHA), and over 22.5 million ASA and AHA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed national coverage determination for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting.

The American Stroke Association is dedicated to improving stroke prevention, treatment, and rehabilitation through research, education, advocacy, and programmatic development. ASA's efforts include the development of scientifically based clinical practice guidelines designed to advise physicians and other providers on the prevention, treatment, and management of stroke, such as "*Primary Prevention of Ischemic Stroke*"[1], "*Guidelines for Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack*"[2], and "*Guidelines for the Early Management of Ischemic Stroke*"[3]. ASA also recently released its "*Recommendations for the Establishment of Stroke Systems of Care*"[4], which addresses the entire continuum of care from primordial prevention to rehabilitation.

As a leading voluntary health organization focused on stroke, the ASA is uniquely qualified to provide the Agency with comments on the proposed coverage determination.

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[1] See http://stroke.ahajournals.org/cgi/content/full/37/6/1583.
[2] See http://stroke.ahajournals.org/cgi/content/full/37/2/577.
[3] See http://stroke.ahajournals.org/cgi/content/full/34/4/1056.
[4] See http://stroke.ahajournals.org/cgi/content/full/36/3/690.

American Heart Association . Advocacy Department
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In the proposed decision memo for PTA with stenting of the carotid artery, CMS proposes to expand Medicare coverage to patients less than 80 years old with asymptomatic carotid artery stenosis ≥ 80% who are at high risk for carotid endarterectomy surgery. ASA has reservations about this proposal. We urge the Agency to return to its current policy that limits coverage to clinical trials and post approval studies for two reasons:

1. The currently available data is not sufficient to conclude either that PTA with carotid artery stenting improves health outcomes – or that it is the most appropriate treatment – for this patient population, and
2. The proposed change will jeopardize obtaining the additional scientific evidence to address this issue. Patients will assume that this is a proven therapy, and that further study is unnecessary. They will be less likely to enroll in ongoing trials or post approval studies.

Current Data is Insufficient

Current Medicare policy restricts coverage of carotid artery stenting in patients with asymptomatic stenosis greater than 80% to participants in clinical trials or post approval studies. This limitation was put in place because of the undocumented natural history of asymptomatic stenosis on medical therapy (the lack of a medical control group in past studies), the lack of long-term data on carotid artery stenting in these patients, and the lack of data on carotid artery stenting performed outside of the controlled trial setting.[5]

In the decision memo, CMS proposes to remove the clinical trial/post approval study restriction citing several recent studies as the basis for its decision. According to CMS, the studies provide sufficient evidence to address the Agency's prior concerns. ASA respectfully, but strongly disagrees with the Agency's assessment; the evidence referenced by CMS is not sufficient to conclude that PTA with carotid artery stenting improves health outcomes for this patient population.

The studies cited by CMS as "sufficient evidence" include four observational case studies and two patient registries; however, CMS acknowledges that its decision was based largely on the industry-sponsored CAPTURE and CASES-PMS registries. ASA believes that the level of evidence represented by these non-randomized registries does not support expanding coverage of carotid artery stenting to asymptomatic patients.

The lack of data is evident in the disagreement among health care professionals over the role of carotid artery stenting for asymptomatic patients. Although PTA has been shown to be effective in some trials involving other organ systems, "there is still debate about its relative efficacy and applicability compared with surgery," according to the AHA/ASA guideline on this topic.[6] It remains unclear how the procedure compares to medical therapy in the high-risk population. According to the *2007 American College of Cardiology Foundation Clinical Expert Consensus Document on Carotid Stenting*, "Management is controversial for asymptomatic patients with

[5] See CMS Proposed Decision Memo (http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=194) Pg. 15.
[6] See AHA Science Advisory: Carotid Stenting and Angioplasty (http://circ.ahajournals.org/cgi/content/full/97/1/121).

severe carotid stenosis who are at a high risk for carotid endarterectomy because they were excluded from the randomized trials of carotid endarterectomy and medical therapy."[7] In fact, CMS itself acknowledges in the proposed decision memo that "…the outcomes of asymptomatic carotid artery stenosis with optimal medical therapy remain unclear and unstudied."[8]

Although PTA with carotid artery stenting may ultimately prove to be an appropriate alternative to carotid endarterectomy or medical therapy in asymptomatic patients who are at high risk for surgery, we do not yet have enough clinical evidence to support or recommend the procedure in this patient population. Well-designed, controlled randomized trials would allow carotid artery stenting to be compared with carotid endarterectomy – what some consider the gold standard in treatment – and with medical therapy.[9] Results from additional trials such as the Asymptomatic Carotid Stenosis Stenting versus Endarterectomy Trial (ACT), Asymptomatic Carotid Surgery Trial (ACST 2), and Carotid Revascularization: Endarterectomy versus Stent Trial (CREST), which are currently in progress, would help the medical community determine the appropriate role for carotid artery stenting for high-risk asymptomatic patients. Without this evidence, it is inappropriate for CMS to remove the clinical trials/post approval requirement for high-risk asymptomatic patients at this time.

Additional Data will be Harder to Obtain

Current Medicare policy limits coverage of carotid artery stenting in asymptomatic patients to those who participate in clinical trials or post approval studies. If the coverage expansion is implemented as currently proposed, this restriction will no longer apply to asymptomatic patients less than 80 years of age. ASA is concerned that removing this restriction will make it harder, if not impossible, to obtain randomized trial (grade A) evidence that compares carotid artery stenting, carotid endarterectomy, and medical therapy – evidence that could support an appropriate expansion in coverage for this patient population and provide physicians with the data they need when advising patients.

Eliminating the clinical trial/post approval study restriction will remove the stimulus for the industry to conduct further studies or trials. It will make it more difficult for researchers to complete trials that are already in progress, including the NIH-sponsored CREST trial, because patients will presume that the "best therapy" is already known and will decline to enroll.

CMS should revise its proposal and reinstate the clinical trial/post approval study limitation until adequate evidence is collected.

Conclusion

In closing, ASA reiterates our concern with the Agency's proposed national coverage determination for PTA of the carotid artery concurrent with stenting. While carotid artery stenting is one potential type of intervention for high-risk asymptomatic patients with carotid artery stenosis $\geq$ 80%, expanding coverage to this patient population would be inappropriate at this time. The data CMS references in the decision memo does not adequately support the use of

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[7] See http://content.onlinejacc.org/cgi/reprint/49/1/126.
[8] See CMS Proposed Decision Memo (http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=194) Pg. 15.
[9] See http://circ.ahajournals.org/cgi/content/full/97/1/121.

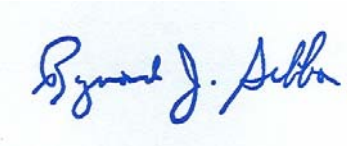
the procedure in this population, and the coverage change would make it more difficult to obtain appropriate scientific evidence about this issue.

Carotid artery stenting in asymptomatic patients should continue to be available only through clinical trials and post approval studies. This would allow patients to be screened for other treatable causes of stroke, evaluated for potential risks, and monitored for health outcomes. Careful patient selection is imperative. Until more substantial clinical evidence is available, carotid angioplasty and carotid stenting, with rare and infrequent exceptions, should be undertaken only as part of a prospective, randomized trial with independent, dispassionate oversight.[10] Continuing to require patients to participate in a clinical trial or post approval study will allow for comparison of a promising intervention with surgical carotid endarterectomy and medical therapy.

We urge CMS to revise the decision memo and return to the current policy which limits carotid artery stenting in asymptomatic patients with stenosis $\geq$ 80% to participants in clinical trials and post approval studies.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Relations Manager, at [redacted] or via email at [redacted].

Sincerely,



Raymond Gibbons, MD, FAHA
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[10] See http://circ.ahajournals.org/cgi/content/full/97/1/121.

The Society for Cardiovascular Angiography and Interventions

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VIA ELECTRIONIC SUBMISSION

March 2, 2007
Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services

RE: Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)

Dear Dr. Phurrough:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a professional association representing over 3,700 invasive and interventional cardiologists. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, and quality initiatives to enhance patient care.

We applaud CMS' expansion of carotid artery stent (CAS) coverage to include the asymptomatic patient at high risk for carotid endarterectomy (CEA). CMS based this on a broad review of the relevant literature, technology assessments, clinical reviews, and post approval studies. We believe this will significantly benefit many patients for whom access was previously restricted. More importantly, it places the conversation between physician and patient squarely back in the appropriate place, namely focused on their clinical care and all of the approved options available to them.

We would like to offer comment on four aspects of the Draft Decision Memo and recommend changes which we believe will better reflect available data and clinical relevance, and strengthen the Final Decision Memo.

1. Facility Accreditation

SCAI greatly appreciates CMS's interest in our proposal to become a recognized accrediting/certifying body for carotid stenting facilities. We believe that our efforts would improve patient care by setting high standards for the training, equipping and monitoring of outcomes at facilities that provide carotid stenting services. Our current plans were identified in the coverage decision and we appreciate CMS placing the plans on their web site for public comment.

We look forward to working with other groups and CMS as we develop this initiative. Over the coming months we will work to develop a working accreditation program and provide evidence to CMS to show that any facilities we accredit will meet or exceed current CMS quality and data standards.

2. Restriction Of Coverage For Patients Who Are Symptomatic And At High Risk For Carotid Endarterectomy To Stenosis >70%,

Before discussing the symptomatic patient in the context of carotid stenting outcomes, it is important to recognize that the natural history for these patients without revascularization is poor. NASCET demonstrated that the risk of recurrent stroke in previously symptomatic patients with carotid stenosis >70% is 26% at 2 years, and for the patients with stenosis 50%-69% is 22.2% at 5 years. While there are no randomized data for the symptomatic patient at high risk for CEA, the presumption is that they have at least the same, if not higher, risk of recurrent events. In fact, the implication from the recently published ACSRS data (Int Angiol 2005;24:221), where asymptomatic patients with severe carotid stenosis >80% and significant comorbidities had a risk of stroke > 6% per year, suggests that the risk of stroke is likely higher for symptomatic high risk patients.

The rationale given by CMS in arriving at this decision largely centered on the results from two recently published European trials, EVA-3S and SPACE. Although the results of these trials are lumped together and referred to as failing to demonstrate non-inferiority of CAS compared to CEA, in reality they are very different trials with different results, and we believe, different conclusions. Importantly, these trials did not include high-surgical risk patients.

EVA-3S was a French trial in patients who were reasonable surgical candidates with symptoms and stenosis >60%. The outcomes for CAS were significantly worse in this study, but both the construct and conduct of this study do not allow an unimpaired interpretation of the results. A critique of the issues in this trial follows below, and we believe that CMS should not base any decisions on this critically flawed non-US based trial.

- Limited investigator experience and number of trained sites/operators
  - Experienced operators defined by 12 lifetime CAS procedures or 5 CAS procedure if 35 supra-aortic procedure (no reports of the use of EPD or the outcomes in these pre-EVA-3S cases)
    - These operators were deemed experienced and allowed to tutor the non-experienced
  - No centralized training qualification process (local proctors pronounced the operators qualified)
- Approximately 2/3 of sites were under tutelage at the beginning of their randomized participation.
- Slow enrollment further limited investigator experience
  - 1.7 CAS patients/year/site
- Early and/or non-standard technique resulted in unnecessary morbidity
  - Use of EPD was not widespread or familiar to many operators
    - Lack of use in the early phase of the trial likely responsible for 4-5 excess strokes (~20% of all strokes in the CAS arm)
  - 5% stent procedure failure requiring emergency surgery in this trial resulting in 2 strokes in the CAS group
    - Major pivotal trials in this country (e.g., SAPPHIRE, ARCHeR) have not reported any emergent surgical conversions
  - No pre-dilation in >80% of procedures (standard in US)
  - Significant (beyond local) anesthesia was employed in ~30% of procedures (estimated <5% in US)

In summary, the practice of CAS in EVA-3S is not at all representative of current practice of CAS in the United States, and data from this trial should not be applied to the standards of practice in the United States.

SPACE was a German trial in patients who were reasonable surgical candidates with symptoms and stenosis >50%. The *prima fascia* outcomes for CAS were comparable to CEA, although the trial was halted since a pre-specified interim analysis determined that more than double the 1200 patients which had already been randomized would be required prove non-inferiority, and the sponsors were not willing to extend the trial further. The authors' conclusion statement that the trial failed to prove non-inferiority should be modified to read that the trial failed to enroll enough patients to prove non-inferiority. Notwithstanding these statistical issues SPACE, which did not use EPD in 73% of patients, nevertheless appeared to show both comparability in outcomes of CAS to CEA in spite of this lack of EPD. Importantly, these patients were not the high surgical risk cohort at issue with this coverage decision, the presumption is that there will be worse outcomes with CEA, as seen in SAPPHIRE, favoring stenting.

It can be seen, then, that in analyzing theses data, it is critical to differentiate "symptomatic" vs. "asymptomatic" and "high surgical risk" vs. "non-high risk" groups, as their outcomes appear to be different. There is peer-reviewed evidence to support CAS with embolic protection as an alternative to CEA in "high surgical risk" patients with symptomatic carotid stenosis ≥ 50% and ≤ 99%. This evidence for non-inferiority and perhaps superiority of CAS to CEA in high surgical risk patients is from a randomized prospective multicenter controlled trial (SAPPHIRE), as well as multiple FDA approved, industry sponsored registry trials in "high surgical risk" patients with symptomatic carotid stenosis ≥ 50% and ≤ 99%.

In summary, the logical progression from NASCET findings of benefit for CEA for symptomatic patients with a greater than 50% stenosis, through the SAPPHIRE results demonstrating the same or better outcomes with stenting compared with surgery in high surgical risk patients, to the comparable results of CEA and CAS (largely without embolic protection) in SPACE suggests that these symptomatic high surgical risk patients will be benefited at least as much by CAS as with the currently covered therapy, CEA.[i]

RECOMMENDATION: Coverage should also be expanded to high surgical risk symptomatic patients under 80 years of age with lesions between 50% and 69%.

3. Requiring a Surgical Consultation

CMS is proposing to now "require that patient's high risk status be determined by a surgeon credentialed to perform CEA". The rationale given by CMS to support this change is also predicated largely on the EVA-3S and SPACE trials, which were normal surgical risk trials only in the symptomatic patient and not the high surgical risk population at issue here. CMS states these trials "demonstrate the risks of CAS and the benefits of CEA when performed by well-trained, highly qualified surgeons". In fact, there is no basis in the data from these two trials to conclude that, in the high surgical risk patient, that there is a difference in outcomes or stroke prevention effectiveness between these two therapies. To the contrary, the outcomes in several Medpar surveys of CEA in this country are sub-standard when compared to those seen in the EVA-3S due to low volume, not specialty-trained (but nevertheless credentialed) nor highly qualified surgeons.

The SCAI recognizes that CAS, like almost every procedure and operation in this country and around the

world, is occasionally done in settings where an operation or medical therapy would be more appropriate, and that it is desirable to deter such activity. That purpose is fulfilled by the facility accreditation requirements that CMS mandates for carotid stenting since validation of reported data will be performed. Using a surgical opinion requirement for such a purpose is problematic at several very fundamental levels:

- A gatekeeper model like this works only when the gatekeeper is uninvolved and unbiased, This is certainly not the case with a vascular surgeon passing judgment on his cardiology, neurointerventional, and radiology colleagues' recommendations.
- The credentialing of surgeons performing CEA is a local phenomenon, and many surgeons so credentialed are not vascular surgical specialists but general surgeons serving their patients and communities by performing CEA, etc. Nevertheless, their expertise in this field may be quite limited, as will be their opinion.
- The bias of the surgeon toward a surgical procedure is obvious and this conflict of interest has the potential to expose patients to an operation (which is still reimbursed by CMS) that has a greater risk of complication than CAS would (e.g., patients with CEA restenosis), and with CMS explicit blessing.
- There are many surgeons who have adopted CAS as part of their practice armamentarium. Are these physicians immune to this rule by virtue of their duality, and thus unconstrained by any oversight?
- The logical extension of the requirement for a surgeon to qualify a patient as high-risk for carotid stenting will be a gradual erosion of other specialty involvement as referring physicians bypass the middle-man.
- The increased cost of these of these consultations will be borne by patients and CMS.
- This could represent a significant workload increase for the surgical community of seeing every high surgical risk patient referred to them for a second opinion considering the estimates of CAS activity in 2006 (~25,000 cases) of which the surgeon was directly involved in only ~25%-30%.
- The need for surgical consultation appears to be excessive given the clear, standardized, retrospectively verifiable definitions already in place through the current national coverage decision (NCD).
- Cardiology consultation for surgical clearance in selected patients with medical co-morbidities is a common, and appropriate, occurrence. The requirement for a surgeon to see these patients to assign risk, the majority are in fact based on medical condition, turns this traditional algorithm on its head; cardiologists are obviously trained to, and fully capable of, determining at-risk surgical patients. Vascular surgeons are not trained to assess the cardiopulmonary risk of these or any other patients undergoing vascular surgery.
- Patients and referring doctors will often object to seeing additional consultants, particularly when patients are referred from physicians from remote areas or other institutions. This is particularly problematic if the patient is responsible for additional co-pay.
- When a cardiologist and a surgeon disagree as to patient risk, does the patient default to a CEA by the surgeon? Is a third opinion to be sought? Moreover, there are significant implications if the interventionalist and the surgeon disagree as to patient risk and there is an untoward surgical outcome, even if there is no fault to ascribe.
- There are no data to suggest that a vascular surgeon provides any benefit to the patient or improves the safety of the treatment recommendation. The CMS requirement for a vascular surgery consultation is therefore not based on any factors to promote patient care or safety.
- It establishes a primacy of one specialty over another in where care expertise overlaps, which is

without precedent in cardiovascular medicine.

- Using the same logic, an interventionalist could be required to evaluate every CEA contemplated in this country for a percutaneous alternative. There is little doubt that there are still high-surgical risk patients undergoing CEA today despite no or unsupportive data, and a potentially safer alternative.
- Finally, and most importantly, the patient is being placed in a vulnerable position by this requirement. Not only will they be the potential position of being caught between specialties in conflict, but they are also very likely to be confused and upset by the differing opinions almost certain to result from multiple, mandatory and unsolicited consultations. The extra traveling involved and the delays in obtaining consultation (which at a recent survey of a vascular surgery department at a major metropolitan hospital was at least two weeks) are typically accompanied by significant anxiety and place significant burdens on family members having to take time out of work to transport/accompany their in definitive therapy. If these issues weren't onerous enough, there will be an excess of unnecessary strokes/deaths occurring as a result of a lack of timely, definitive therapy. Besides the obvious disability and disrupted lives, the potential liability issues for all involved are significant.

RECOMMENDATION: CMS should eliminate the current proposed requirement of mandatory surgical opinion

4. Non-coverage of a procedure where it is not possible to place an embolic protection device after an unsuccessful attempt at placement is not technically feasible.

There is no discussion in the CMS Analysis section providing rationale for this proposed change to the NCD.

The SCAI believes the use of embolic protection devices (EPD) during carotid stenting likely improves outcomes, and teaches its routine use during SCAI educational programs. However, there are (infrequent) times when the use of EPD poses more risk than proceeding without it. In fact, current, soon-to-be-published data from the CAPTURE registry has determined that the use of pre-dilation in continued attempts to place EPD is one of 4 independent predictors of adverse outcomes (the others: symptomatic status, octogenarians, and multiple stent use). We are concerned that operators will be inappropriately aggressive in attempts to place EPD based on this proposed change, and it will result adverse outcomes in the Medicare population and is clearly contrary to the intent of CMS.

We do not disagree with CMS's plan to not cover procedures where the deployment of embolic protection is not attempted. To prepare for the possibility that half way through a procedure it will become a non-covered service (unless the procedure is aborted) should all patients be given advance beneficiary notices stating that, if the deployment of embolic protection fails and their physician continues with the procedure they will be liable for all of the costs of the procedure?

It may in fact be appropriate to abort a procedure when the operator determines that the risk of proceeding is greater than either the medical or surgical alternatives; however, there are many scenarios where an unprotected CAS would be more appropriate than an operation or medical therapy (e.g., a symptomatic patient with prior radical neck surgery, radiation, and a tracheostomy) if its placement were problematic. This calculus is, however, individualized for each patient (and operator to a certain extent), and the CMS requirements to abort a procedure remove that important decision making capability.

<u>RECOMMENDATION:</u> The SCAI proposes that the proposed change in the requirement of EPD for coverage be removed, and the prior language regarding EPD be restored

<u>5. Data Collection Requirements</u>

SCAI supports CMS's proposal to accept participation in the CARE Registry™ ?and other national registries as a sufficient methodology to meet CMS' data collection requirements for facility certification and recertification. We support CMS's emphasis on regular data collection and analysis as a way to continuously improve the care provided to Medicare and other patients receiving CAS procedures. Given the demands upon hospital data collectors, we also appreciate that facilities enrolled in CMS approved national carotid artery stenting registries will automatically meet these data collection standards required for initial and continued facility certification.

<u>Conclusion</u>

These comments were developed with the guidance of the Christopher Cates, MD, FSCAI, Michael Cowley, MD FSCAI, William Gray, MD FSCAI, Kenneth Rosenfield, MD FSCAI, Robert Safian, MD, FSCAI, Bonnie Weiner, MD, FSCAI. They comments were reviewed and approved by the SCAI's Executive Committee and by me. We look forward working closely with CMS in refining this coverage policy and in the development of the SCAI CAP. Please coordinate our communications with SCAI's Senior Director for Advocacy and Guidelines. He may be reached at [redacted] or by email at [redacted]

Sincerely,

Gregory J. Dehmer, M.D., FSCAI
President

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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March 2, 2007
CMS, via e-Mail
CAGinquiries@cms.hhs.gov
Re: PTA of the Carotid Artery Concurrent With Stenting
CAG-00085R3

The Blue Cross and Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) appreciates the opportunity to provide comments on the National Coverage Determination of PTA of the Carotid Artery Concurrent with Stenting. These comments are offered on behalf of the 38 independent Blue Cross and Blue Shield Plans belonging to the Blue Cross and Blue Shield Association that collectively provide health benefits to almost 98 million members- one in three Americans

The TEC Medical Advisory Panel (MAP) considered a TEC assessment of Angioplasty and Stenting of the Cervical Carotid Artery With and Without Embollic Protection of the Cerebral Circulation on February 21, 2007. The draft assessment is attached to this e-mail. The TEC assessment concluded that the available evidence does not support concluding that carotid artery stenting (CAS) is performed with acceptable periprocedural stroke/death rates for symptomatic or asymptomatic patients, that it provides a net health benefit to high medical risk patients, or is equally effective as carotid endarterectomy. The MAP found that use of carotid artery angioplasty and stenting with or without embolic protection of the cerebral circulation for patients with carotid artery stenosis does not meet the BCBSA TEC criteria.

TEC believes that two fundamental questions must be considered. The issues they raise are critical to determining whether current evidence supports the NCD, proposed changes, and adequately defines subgroups benefiting from carotid artery stenting (CAS). These questions, relevant issues, and some pertinent evidence are discussed in turn.

1. Can CAS be performed with acceptable periprocedural stroke or death rates such that it results in a net health benefit among symptomatic or asymptomatic patients at:

- *a. average medical/surgical and anatomic risk,*
- *b. increased medical/surgical risk, or*
- *c. increased anatomic risk?*

For CAS to provide a net health benefit it must be performed with periprocedural complication (stroke or death) rates equal to, or less than, those established for carotid endarterectomy (CEA). Acceptable complication rates are well-defined based on pivotal trials (NASCET Steering Committee 1991a 1991b; ECST Collaborative Group 1991; Barnett et al. 1998; ECST 1998; Mayberg et al. 1991; ACAS 1995; Hobson et al. 1993; Halliday et al. 2004) and reflected in evidenced-based guidelines articulated by both the American Heart Association (Biller et al. 1998, Sacco et al. 2006) and American Academy of Neurology (Chaturvedi et al. 2005). These periprocedural complication rates are less than 3% for asymptomatic stenosis (60 to 99%), and less than 6% for symptomatic stenosis (50 to 99%); exceeding

those rates risks negating potential benefits from CAS or CEA. The benchmarks are of particular importance among asymptomatic individuals where the absolute benefit is the smallest and symptomatic individuals with moderate stenosis (50 to 69%) (Gorelick, 1999).

CAS is currently recommended for patients at "high risk" of undergoing CEA. Yet "high risk" has generally not been defined with adequate specificity because studies fail to distinguish outcomes according to medical/surgical or anatomic risk. This hampers defining the patient subgroups most likely to benefit from, or harmed by, CAS or CEA. For example, there is a clinical rationale to suggest CAS may be beneficial in the group of patients at high anatomic risk (e.g., surgically inaccessible lesions, unfavorable anatomy, prior radiation or neck surgery, spinal immobility, laryngeal nerve palsy, restenosis). However, among reports from trials and registries, to our knowledge few have reported outcomes for the subgroup at increased anatomic risk (e.g., White et al. 2006).

2. How do CAS, CEA, and optimal medical therapy compare in the subgroups at increased medical/surgical or anatomic risk?

Defining the role of CAS in groups at increased medical/surgical or anatomic risk requires not only comparison to CEA, but also to current optimal medical therapy (which has improved since pivotal trials were conducted) because of the potentially narrow risk/benefit ratio for either procedure in some subgroups—particularly asymptomatic patients.

A brief view of existing evidence for these subgroups is instructive in considering these questions. Among the asymptomatic "high risk" patients in SAPPHIRE (Yadav et al. 2004) ($\geq$ 80% stenosis) the periprocedural complication (stroke/death/MI) rate in the CAS arm (n = 117) was 9.2% and periprocedural stroke rate 5.1%. SAPPHIRE did not report results (comparing CAS and CEA or otherwise) separately according to medical/surgical or anatomic risk. Three registries enrolling "high risk" individuals have reported outcomes according to presence or absence of symptoms (combined n = 4,015); periprocedural complication rates in the asymptomatic groups ranged from 5.0 to 5.4% (ARCHeR, Gray et al. 2006; CAPTURE, Gray et al. 2006a; BEACH, White et al. 2006). Results presented from the credentialing phase of CREST reported a periprocedural stroke or death rate in asymptomatic patients of 3.4% (95% CI: 2.3 to 4.9%)—a sample of 1246 asymptomatic and symptomatic patients combined (Roubin et al. 2006).

Both SPACE (Ringleb et al. 2006) and EVA-3S (Mas et al. 2006) enrolled symptomatic patients not specifically at "high risk"; periprocedural stroke or death rates with CAS were 7.3% and 9.6% in the two trials respectively. While in SAPPHIRE, complication rates were low among symptomatic patients undergoing CAS (2.0%) there were only 50 patients and 1 event making inferences problematic (also recognizing the study was not powered to examine subgroups). In the symptomatic groups from ARCHeR, CAPTURE, and BEACH (combined n=807) periprocedural stroke or death rates ranged from 7.9 to 12.1%, while the CREST abstract reported a rate of 5.6% (95% CI: 3.3 to 8.7%).

To our knowledge, only published data from the BEACH registry (White et al. 2006) reported outcomes according to whether patients were considered at increased anatomic or medical/surgical risk. The periprocedural complication rate was lower in the group at increased anatomic (n=456) as opposed to medical/surgical risk (n=289)—3.5% versus 5.9%. However, the report did not stratify these results further by the presence or absence of symptoms.

In conclusion, although data are accumulating rapidly, it is our view that current evidence does not demonstrate CAS can be consistently performed with periprocedural complications rates likely to provide a net health benefit. We encourage CMS to require reporting outcomes from all studies according to presence or absence of symptoms, medical/surgical or anatomic risk, and degree of stenosis. Long-term follow-up for neuropsychological (cognitive) outcomes is also critical; we recommend CMS include them in required reporting. The potential benefit and role of CAS in the treatment of carotid atherosclerotic disease requires clear definition that current evidence does not provide.

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Sincerely,

Allan M. Korn, MD, FACP
Senior Vice President Clinical Affairs and
Chief Medical Officer.

March 2, 2007

Steve Phurrough MD, MPA
Director, Coverage and Analysis Group
Marcel Salive MD, MPH
Director, Division of Medical and Surgical Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

Dear Drs. Phurrough and Salive:

The undersigned organizations wish to respond to the proposed NCD revision (CAG-00085R3) related to carotid artery stenting (CAS).

CMS proposes 3 changes to the NCD:

1) Restrict the current coverage for patients who are at high risk for carotid endarterectomy (CEA) and have symptomatic carotid artery stenosis > 70% to patients who are less than 80 years of age.

We disagree with this change. There is insufficient evidence to limit CAS to patients under age 80 who are symptomatic and therefore at high risk for stroke. In its proposed NCD, CMS cited literature documenting an increased morbidity and mortality for CAS in patients over the age of 80. Stanziale, et. al., and the report from the CAPTURE registry documented rates of stoke, death or MI of 9.2% and 9.4% respectively in patients over the age of 80 undergoing CAS. These rates were significantly greater than the rates for patients under 80. While this is compelling data that should be considered in every patient over the age of 80 who is being considered for CAS, it does not necessarily negate the potential benefit of this procedure in all patients over the age of 80. The natural history of medical management of patients with severe stenosis documented in NASCET, estimated two year ipsilateral stroke rates of 26% for this age group.

The proposed change to the NCD would limit access to potentially life saving therapy in this group of patients who have limited other options.

2) Expand coverage to patients who are at high risk for CEA and have asymptomatic carotid artery stenosis >80% and are less than 80 years old.

We disagree with this change. The undersigned unanimously agree that the evidence is currently insufficient to support coverage for CAS in asymptomatic high risk patients.

In order to show a net benefit in asymptomatic patients the accepted 30 day stroke + death rate in average risk patients must be < 3% based on ACAS and ACST. The additional studies cited by CMS since the original 2005 NCD, which was limited to symptomatic high risk patients, are case series or industry sponsored registries; none is a randomized controlled trial. The 30-day major event rates (mostly stroke) in the 3 largest studies cited (CAPTURE, CASES, Safian etal) were: 6.8%; 4.5%; and 6.2% respectively. In the largest registry, CAPTURE 3500, the 30-day stroke + death rate even in patients under age 80 was 4.1%.

Beyond procedural risk, as treating physicians we believe it remains unclear whether, in high risk asymptomatic patients, CAS or CEA is superior to concurrent medical therapy. CMS itself acknowledges that "…the outcomes of asymptomatic carotid artery stenosis with optimal medical therapy remain unclear and unstudied." Thus, while subjecting asymptomatic patients to a significant procedural risk of stroke, without concurrent medical controls or a better understanding of the **multiple** natural histories comprising the high risk subset it is impossible to determine if the procedural risk can be justified by any long-term benefit.

At the time of the 2005 NCD, CMS challenged the medical community to gather outcomes data in medically treated asymptomatic high risk patients. This has not occurred for several reasons. There are 15 conditions lumped together under "high risk." Five of these are cardiac; some are anatomic (e.g. high cervical bifurcation; contralateal occlusion; restenosis); some are related to malignancy (prior neck irradiation); and some involve other major organ dysfunction (renal, pulmonary). There may also be special circumstances such as patients requiring coronary intervention with concomitant carotid stenosis. The long-term benefit of CAS compared to best medical therapy is likely to differ for these various conditions and it will be impossible to conduct a RCT for each condition. **Specific guidelines should be developed for each major high risk category**. At a minimum these high risk criteria patients should be divided into 2 groups: those with less than 5-year life expectancy and those with greater than 5-year life expectancy based on actuarial or other objective natural history data. Other barriers include the lack of funding for medical outcomes proposals, the difficulty of conducting a randomized controlled high risk CAS trial which includes a medical arm, the mistaken belief that efficacy data can be provided through registries and that registry data will be sufficient to obtain expanded coverage.

Since CEA is already reimbursed and CAS appears at least as safe as CEA in high risk patients, CMS is obligated to address this disparity in coverage. One approach is to argue that since CAS is at least as safe as CEA in high risk patients, and CEA is already reimbursed, then CAS should also be reimbursed. The fallacy of this argument is that the coverage of CEA is not based on high risk trials but on average risk CEA trials such as NASCET, ECST, ACAS and ACST. Indeed, the term "high risk" specifically applies to high **surgical** risk and such patients were excluded from prior CEA trials. The 30 day adverse event rates in SAPPHIRE were actually higher among asymptomatic patients than among symptomatic high risk patients. In SAPPHIRE the 30 day stroke and death rate in high risk, asymptomatic patients undergoing CAS versus CEA was 5.4% versus

4.6% respectively. If acute myocardial infarction is included, the 30 day adverse event rate in asymptomatic high risk patients was 5.5% for CAS versus 10.2% for CEA. **These results suggest a >3% 30 day stroke and death rate for both CAS and CEA in high risk asymptomatic patients but are based on a single underpowered RCT (SAPPHIRE). The apparent excess risk for CEA compared to CAS was due solely to myocardial infarction and cannot necessarily be extrapolated to other high risk subgroups.**

The 2007 ACCF/SCAI/SVMB/SIR/ASITN Clinical Expert Consensus Document on Carotid Stenting (J Am Coll Cardiol, 2007; 49:126-170, doi:10.1016/j.jacc.2006.10.021) states: "Management is controversial for asymptomatic patients with severe carotid stenosis who are at high risk for CEA because they were excluded from the randomized trials of CEA and medical therapy. There are insufficient data in these high-risk patients to define the natural history of medically or surgically treated disease with respect to 5-year stroke-free survival, although the risks of CEA are clearly higher than in low-risk patients. It is important to recognize that the benefits of revascularization are negated if the risk of revascularization is high, and the fact that CEA is associated with more risk does not mandate that patients undergo CAS. There is a real need for additional studies of high-risk asymptomatic patients who are treated with best medical therapy, since this could be the best treatment option. In the meantime, to gather additional data, it is reasonable to enroll these high-risk patients in nonrandomized registries."

There is thus broad expert consensus across many disciplines that there is insufficient evidence regarding the relative risk of CAS versus CEA in all asymptomatic high risk subgroups or that either procedure is superior to best medical therapy. Accordingly, it would be inappropriate and not in the best interest of patient care to change the CAS NCD to include asymptomatic high risk patients in any age group at this time. It would be appropriate for CMS to review its policies regarding CEA in high risk asymptomatic patients. The below-signed members of the Neurovascular Coalition recommends that both CAS and CEA be performed in high risk asymptomatic patients only within a randomized clinical trial or other scientifically accepted methodology containing a medical control arm and statistically powered to determine efficacy.

The proposed NCD revision could also significantly impede the completion of average risk efficacy trials such as CREST and ACT I. Completion of these trials is essential to determining the appropriate utilization of CAS.

3) Establish that the surgeon performing the surgical consultation that determines a patient's high risk status must be properly credentialed to perform CEA as determined by the facility.

We agree with this change.

4) CAS is only covered when used with an embolic protection device and is, therefore, not covered if deployment of the distal embolic protection device is not technically possible.

We disagree with this clarification. An embolic protection device (EPD) should be used where technically feasible but reimbursement should not be contingent on use of an EPD. If an EPD is not used, the interventionist must document the reason

5) The five facility certification requirements are unchanged. We propose to modify the process for completing the certification and recertification process in the NCD Manual.

Regarding the potential transfer of authority for certification and recertification of facilities performing CAS, we are opposed to the proposal that these functions would be performed by the Society for Cardiovascular Angiography and Interventions (SCAI). Although the SCAI is comprised of members dedicated to vascular interventions, the vast majority of such interventions involve the coronary and peripheral vessels. SCAI does not represent neurology, neurosurgery or neuroradiology. Oversight of certification and recertification of facilities must be performed either by a neutral body or a body representing all appropriate medical specialties. We are willing to discuss development of such a multidisciplinary approach with you.

In conclusion, we wish to emphasize the multidisciplinary breadth of the organizations participating in this response including the major societies representing Neurology, Neurosurgery and Neuroradiology.

Sincerely,

American Academy of Neurology, Member, Neurovascular Coalition

American Association of Neurological Surgeons, Member, Neurovascular Coalition

American Society of Interventional & Therapeutic Neuroradiology, Member, Neurovascular Coalition

American Society of Neuroradiology, Member, Neurovascular Coalition

Congress of Neurological Surgeons, Member, Neurovascular Coalition

AANS/CNS Cerebrovascular Section, Member, Neurovascular Coalition

Invited Co-Signer,

Brain Attack Coalition

February18, 2007

Steve Phurrough, M.D., M.P.A.
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RE: ADMINSTRATIVE FILE, CAG 00085R3
PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF CAROTID ARTERY CONCURRENT WITH STENTING

SUBJECT: PROPOSED COVERAGE DECISION MEMORANDUM FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF THE CAROTID ARTERY CONCURRENT WITH STENTING – PROPOSED DECISION STATEMENT PUBLISHED 2/1/2007

I am writing as an individual commenting on the proposed carotid stent decision with my recommendations being based on affiliations that I have with national societies interested in this decision, clinical trials addressing the utility of this technology, and my knowledge of the interactions between the federal agencies and physicians dealing with this NCD.

I begin this discussion by acknowledging that broadening the decision has several advantages to me personally. I am a practicing vascular surgeon who has privileges for both carotid endarterectomy and carotid stenting, including an investigator IDE that is approved for evaluation of both asymptomatic and symptomatic patients with carotid occlusive disease. My private practice, which has a referral pattern for these patients, would be significantly enhanced by the current proposed decision that adds the high-risk, asymptomatic greater than 80% stenosis patients. Not only would I benefit financially from reimbursement for increased number of clinical cases, I would also have advantages related to training of physicians for expansion of this technology. My current practice would also be significantly simplified by eliminating a large volume of regulatory documents and clinical support staff that are require to continue the investigator IDE.

I have other affiliations that may be viewed as a conflict of interest. I was the principal investigator for the CARESS Phase 1 feasibility study sponsored by the International Society for Endovascular Specialists, which has evaluated the utility of carotid stent technologies compared to carotid endarterectomy in a clinical practice model including both asymptomatic and symptomatic patients. After many years of effort regarding initiation and completion of the feasibility study, a CARESS pivotal study addressing the broad label utility of these devices is planned in the near future. I am also a member of the Society for Vascular Surgery Outcomes Assessment Committee and have been involved in the development of the SVS Carotid Stent Registry which emphasizes the importance of long-term surveillance and outcome assessment for carotid endarterectomy, carotid stents and medical therapy for extracranial carotid artery occlusive disease.

In spite of the personal advantages I have described if the current coverage is expanded to include the greater than 80% asymptomatic high-risk patients for carotid stent reimbursement, this would be done <u>without the scientific data required to support this position</u>. It has taken many years to get several commercial studies and post-market registries focusing on assessing the outcome of low and medium risk patients. The current reimbursement policies of CMS to fund these studies and provide the data needed to make a sound scientific decision has empowered these critical studies. If the current proposed coverage is established, the low and medium-risk studies will no longer be of interest to investigator's and the opportunity to establish science related to this topic will be abdicated. I must emphasize that the critical nature of the current environment where manufacturers and investigators have finally committed to performing studies that would evaluate low and medium- risk patients, would be terminated by this approval and <u>this is clearly not in patient interest</u>.

My second comment is that restriction of payment in all patients greater than 80 years of age denies a Medicare benefit to a subset of patients who are greater than 80 years of age who would benefit from carotid stent therapy. The scientific data that is available to support restriction in the greater than 80 age group is particularly limited, with some of the data being acquired in the learning curve phase of studies of new devices, and evolving clinical studies. Larger, broad-based population studies performed by experienced investigations, as is beginning to occur in the current environment and in studies that are about to be initiated, will provide appropriate data to clarify unresolved issues.

I close this discussion by commending the CMS team for their ongoing intensive assessment of issues related to this topic. The group, headed by Dr. Phurrough, has established a new precedent in the evaluation and payment of devices based on carefully designed scientific studies. The current decision is a prototype for future technologies. Although my opinion regarding these decisions may be reflected in other documents that will come to the agency from national societies and other efforts described above, I again reiterate my personal opinion

is that broadening the decision to include high-risk, asymptomatic patients with greater than 80% stenosis abdicates a unique opportunity to acquire the scientific data needed to appropriately support this decision, and in the current environment is not in patient interest. The current and proposed studies that are about to begin to study broader application of this technology will never be completed. No Medicare beneficiary is currently being denied the opportunity for best therapy if they are willing to participate in proposed clinical trials that would be reimbursed by the current NCD. I would ask you to not modify the decision other than to possibly increase coverage for anatomic high-risk patients, and to continue to current clear directive for scientific evidence before NCD decisions are made.

Thanks for considering my opinion.

Sincerely Yours,

Rodney A. White, M.D.
Chief, Vascular Surgery
Associate Chairman, Department of Surgery
Harbor-UCLA Medical Center
Professor of Surgery
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RAW:gs

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February 23, 2007

U. S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Medicare Coverage Center
mailto:caginquiries@cms.hhs.gov

Re: Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

Dear Sir or Madame:

On February 1, 2007 CMS issued a Summary of Proposed Changes to modify the national coverage determination (NCD) for carotid artery stenting. On page 23 of the February 1 document CMS indicates that they believe…"data clearly demonstrates the need for an expert opinion and we are thus proposing that we modify the standard to require that the patient's high risk status be determined by a surgeon credentialed to perform CEA." I believe that changing the NCD in this manner will be a mistake and I offer the following comments for your consideration.

Cardiologists clearly have the training and experience to make expert clinical judgments regarding the risks and benefits of CAS and CEA. Cardiologists are coming out of fellowships with this training. There is a 30 year history of percutaneous experience in the discipline of cardiology. A cardiologist is also more capable of rendering an expert opinion as to the patient's medical stability and readiness for CEA.

The proposed changes to the NCD do not lay out next steps when a cardiologist and a surgeon disagree on a treatment plan. Does the surgeon's opinion trump the cardiologist's? Is a third opinion sought? Patients and family members will be confused and upset by differing opinions. To have one specialty reign over another is unprecedented in medicine when two disciplines overlap and both are capable of making sound clinical judgments. Furthermore, a gatekeeper arrangement only makes sense if the keeper of the gate is a neutral party. A surgeon may have a bias toward a surgical intervention which in some patients may propose a greater risk of complications.

The current NCD already provides appropriate and retrospectively verifiable coverage guidelines. Due consideration should also be given to the extra cost of these consultations to be borne by patients. Finally, and most importantly, delays in scheduling these consultations may result in otherwise avoidable strokes and deaths.

Immanuel Medical Center
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10020 Nicholas St. #202
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(402) 391-5055

The surgical opinion requirement is flawed because it is unnecessary, costly, confusing and puts patients at risk. I ask that you please reconsider your position on this issue.

Respectfully submitted,

Michael M. Dehning, M.D., F.A.C.C.
President
Heart Consultants, P.C.
6901 N. 72nd Street, Suite 3300N
Omaha, Nebraska 68122

[redacted]

The determination of the patients risk status regarding CAS is sommething that not only vascular surgeons can perform. Those interventional cardiologists, radiologists, neurointerventionalists are also capable of making the correct determination. Any professional who consults on a case should be qualified to make a risk assessment for CEA vs CAS. The physician that consults should be priveleged to perform the procedure in question. It should be incumbent on the specialist to assist in making the correct choice based on all the clinical data.
Thank you,
Christopher Rogers D.O. FACC, SCAI

I am a board certified Vascular Surgeon.

This feedback is in relation to the proposal to further regulate carotid stenting by making it a requirement for a surgery credentialed in CEA. This is not only the best way to regulate the unchecked stenting of non-high risk individuals, but will also allow for better quality control and follow up of these patients. To date, I have seen 4-5 pts in the last year under the age of 60 who have had carotid stents placed without high risk categorization in my vascular specialist opinion. In fact, some probably would not have reached my criteria for any intervention whatsoever.

Cardiologist and interventional radiologists ARE NOT vascular specialists and are really not qualified to determine if a pt is a high risk since they do not offer the alternative,more permanent, more tested and researched option of CEA. I do believe stenting should be an option, but it has been my experience, that VERY FEW patients are of a high enough risk to eliminate the possibility of a carotid under local anesthesia.

Having a check on the system that incorporates the individuals who pioneered CEA for stroke reduction is needed and should be required by CMS. "Not inferior to" as the studies have shown is not always the best procedure for the patient....protecting the choices of the patient with their lack of medical knowledge about this issue is paramount.

Thank you.

Ralph Burton Pfeiffer III MD
102 Sawgrass Drive
Dothan, AL 36303

It is my opinion that a cardiologist is in the best position to make a determination regarding the patients overall risk for a surgical carotid procedure. Although the surgeon can and should provide an assessment, the final "clearance" usually rests with the internist and/or cardiologist and therefore there should be no requirement that a patient be deemed "high risk" by a vascular surgeon.

I think that the consultation of a vascular surgeon to determine the degree of CEA risk should be optional. There are of course anatomical reasons based on which the risk of CEA may be high. In this case a surgical consultation is very important. However, in other cases when the high risk is primarily determined by the presence of other comorbid conditions ie CHF, severe CAD etc, the surgical consultation may be redundant.

I am an interventional cardiologist and I take strong exception to the requirement proposed of getting a surgical consult from a vascular surgeon who is certified in performing CEA.

Most vascular surgeons in our community are likely to have a biased opinion as they will not want to lose control of the patient and the procedure.

Dear Sir/Madam,
The determination of who is suitable for stenting should be based on established guidelines from a multidisciplinary panel not the whims and fancies of ONE surgeon at ONE location however well trained, credentialed or otherwise. This is a matter of public and health policy and should not be unduly influenced by one persons bias or local prefrences. The bias of an individual surgeon or interventional cardiologist/radiologist is the same though perhaps and at times in opposing directions---BOTH should be avoided. WE need national consensus not local politics please! As a govt organization your mandate should be to establish this and NOT open an even bigger can of worms by allowing the surgeon individually to make the screening decisions.
S.Sanjay Srivatsa MD FACC FACP FSCAI

Dear members,
As an interventional cardiologist with extensive formal fellowship training in peripheral vascular disease, I feel compelled to comment on the “vascular surgeon” consult to determine a patients high-risk status. Cardiologists clear more patients for surgery than any other specialty in medicine. We have been trusted to deem patients high, intermediate, or low risk for a variety of surgeries and procedures. Now I need a vascular surgeon to tell me if a patient is a high vascular surgery risk…there is a rather obvious disconnect in this thought process. Perhaps I should have to be consulted prior to all fem-pop bypasses, to decide that there is not a reasonable percutaneous approach! I think our vascular surgery colleagues would flip! I think you are getting on a slippery slope that is unnecessary and inflammatory. I hope you reconsider this aspect of your proposal.

Respectfully,
Bruce S. Bowers, MD
Baylor Health System

I think requiring an interventional cardiologist to refer a patient to a surgeon for a decision on whether the patient is high risk is ridiculous and unprecedented.
Cardiologists have long been asked to risk stratify patients for vascular surgery, peripheral and coronary for years. We are constantly consulted for preoperative evaluations for many surgeries and asked to clear patients for the proposed procedure.
I think that if any referral is required, it should be that the surgeon should refer the patient to a cardiologist for a decision on whether it is a high risk patient or not.
I believe that experienced operators who have good out comes can determine which treatment modality is best for the patient. Never before has a referral been required to be made by a surgeon prior to them operating that I am aware of.
This will only complicate and increase the expense of medical care.
Please use some common sense and do the right thing and allow this procedure to be done by people who are properly trained, do good work, and have spent the last several years using and learning this modality.
A review of outcomes would be a way to allow someone to continue to use the procedure, but I believe that all good physicians will try to do what is best for their patients whether they are the ones performing the procedure or are referring the patient to another physician.
Thank you for your time and I will be glad to discuss this further with you in the future.
Chris Waterer, M.D.

Consultation with a surgical colleague MANDATED by the federal government seems overly burdensome. Our goal should be optimal care of our patients, not forced consultation, at added expense and inconvenience to the patient.

Mark Stankewicz

The proposed CAS requirement for consultation prior to stenting with a surgeon credentialed in CEA is both burdensome and unwarrented. The impact to patient care is to create an unnecessary delay for consultation. Surgeons consult medicine (Cardiology) for assessment of surgical risk. It would be unusual to then have medicine (Cardiology) consult surgery for assessment of CAS/CEA risk. Seems silly to reverse rolls when the non-surgeon is already the person to assess for surgical risk for all other patients.

It is too burdensom to require ALL patients to consult with a surgeon prior to proceeding with carotid revascularization.
We need to make a difficult situation as easy for patients as possible. And what about patients preferences.

The CMS decision is based on pitting one physician against another, is amoral. lacking in all aspects of medical ethics, and smacks of econimic savings incentives for the payers of

healthcare. When you can honestly say this is what you would want for your own mother, maybe some one will believe you. A Troy, MD, FACC. FSCAI

I am curious about a Federal mandate for consultation to assess risk priot to CAS (carotid artery stenting). Is there a precedent whereas one group of physicians are mandated to consult with another that in effect "competes" with one another. Thank you for your time. Sincerely

Chris Y. Kim MD, FACC.

I understand the data very well, but I don't think a vascular surgeon will be 100% unbiased in individual patient assessment re: high vs low risk. The impact of this might be catastrophic to our practices when it looks like "we have to get the permission" of the surgeon prior to CAS!

I have been very pleased with the Medicare coverage process for carotid stenting thus far as I felt it balanced greater access with greater saftey. The current proposal that all carotid stent patients will require a surgical consultation first will limit access and have the potential of less safe patient care as high risk patients may go to surgery. The excellent collaberation we have now is in part driven by all parties involved being equally able to make decisions without the "need" for another specialty to oversee their decision making. Now, patients get the best of all specialties. A system where one specialty presides will have patients pulled between physicians or gaining multiple consultations when physicians disagree. The patient will end up confused, less confident, and potentially with the wrong procedure.
Thank you, Peter Higigns, M.D.

I am very concerned with CMS's requirement mandating "surgical" consultation prior to CAS in accordance with the patient requirements.

Rather than mandating a surgical consultation, it would be far more appropriate to mandate a Vascular Medicine consultation, Neurologic consultation, or Cardiovascular consultation. I am quite confident that a Vascular Surgeon is not more qualified at assessing "high risk" than someone with Internal Medicine /Cardiovascular disease training. In fact, the vast majority of vascular surgeons ask for pre-operative consultation from a Cardiovascular specialist, not vice versa!

I am commenting to express my support for expanding Medicare coverage for carotid stenting for high-risk patients. Specifically, I feel that asymptomatic patients with greater than 80 percent stenosis should be included. Furthermore, I feel that age greater than 80 should be considered high risk.

I base my comments on more than than 2 years experience with carotid stenting, having performed several hundred procedures. We have participated in ARCHeR, Beach, EXACT, CASES and Capture carotid stent trials, and are currently enrolling in Capture II and ACT I trials. The results of the Sapphire study clearly show that carotid stenting is superior to CEA in high-risk patients, even if they are asymptomatic. The post-market studies show that carotid stenting can be safely performed. The majority of patients in these studies were asymptomatic. To exclude these patients from coverage would subject them to a higher risk procedure.

I would like to express a strong position against requiring that a surgeon determine the high-risk status of carotid stent patients. The criteria that determine high risk have been well established in all of the pre- and post-market trials. Most of these trials required a neurological evaluation but not a surgical consultation. The proposed requirement would make the procedure cumbersome and more expensive.

Thank you for the opportunity to express my concerns.

I think this proposal is skewed in favor of vascular surgeons since it puts the ultimate decision in their hands. This is unreasonable since it is still a matter of intense debate as to whom is better equiped for performing carotid artery stenting: a vascular surgeon highly trained in cutting and sewing or an interventional cardiologists highly trained in catheter manipulation and stenting. Carotid artery stenting is a highly complex proceedure involving a myriad of catheters, wires, balloons, and stents. It does not involve cutting or sewing. That pretty much speaks for itself. Thank you.

The proposal for a mandated surgical consultation is a regressive, not progressive attitude regarding the future of carotid stenting (CAS). Those of us performing this procedure in the community have experienced outstanding success with CAS. The key components of favorable outcomes is a skilled endovascular operator(I am an interventional cardiologist with 20,000 catheter-based procedures in my wake), with sound clinical judgement, and adherence to the paradigm of, "patient's best interest". The procedure of CAS has created an intense turf battle in many communities between surgical and catheter based physicians and their care for patients with carotid disease. In my own community this rift has become vicious and associated with personal attacks. Perhaps, my success with CAS (100 procedures without a procedure related death or stroke)has fueled this viceral response from my surgical collegues. Given this acrimonious milieu, the proposed mandate will occur with a serious conflict of interest. One can historically reflect upon the genesis of coronary angioplasty (PCI) and understand how any proposal of a mandated cardiac surgical consulation before the performance of PCI, would have been associated with the same level of conflict and dysfunction. Evidenced based medicine to

date indicates that CAS is clearly not inferior to CEA; furthermore, experience in the real-world (CAPTURE trial)supports the success of this procedure with community based operators.
As a physician practicing cardiovascular medicine for 20 years my sense is that CAS will prove to be an acceptable option as first line therapy for most patients with carotid disease. Based upon the evidence to date and my own personal experience with the procedure, CAS should be viewed as a major advancement in the care for patients with extracranial vascular disease. CAS has passed the "family test" for me....given the option of CEA vs CAS for one of my family members, CAS would be the unequivocal choice! The CMS proposal for mandated surgical consulation will only serve to delay the inevitable.

Respectfully

Mark M. Bernardi, D.O., FACC, FSCAI, FACP
Wilkes-Barre, PA

I am an interventional cardiologist and I agree totally with you, I have seen patients labeled high risk when they are not, I have seen cardiologist perform carotid stents on asymptomatic carotid lesions less than 50%(I can give you specific example if you need). Unfortunately some of us can not police themselves and need an objective surgical opinion.
thanks.
Bassam Al-joundi,M.D.,FACC

I believe that mandating surgical consultation for potential carotid stent patients is wrong and an impairs my ability to properly treat patients. I see many patients undergo CEA who should undergo CAS due to known high risk criteria. If you mandate that all CAS stent patients need a surgical consultation, then you should also mandate that all CEA patients get a consult from an interventionalist.

Let's stop making CAS a political debate and follow the recommendations from the clinical trials!

I personally do not perform carotid artery stenting. However, I do not feel that federal mandate of surgical consultation as a requirement for performing this procedure is appropriate. This sets a burdensome and costly precedent for second guessing physician judgement.

To whom it may concern,
I am a board certified vascular surgeon with a large experience in both carotid endarterectomy (CEA) and carotid stenting (CAS). I have the following comments about the proposed changes in the CMS guidelines:

1. I agree that current data does not support CAS for patients over the age of 80.
2. I believe it is mandatory that a surgeon versed in CEA be asked to confirm inoperability. I have been chagrined to see how many quite operable patients suddenly have been labeled “high risk” by interventionalists (surgeons, cardiologists and radiologists) keen on increasing there numbers of CAS. This is clearly unconscionable and must be controlled. I suspect that this requirement may not be feasible in certain institutions and may create animosity amongst the various practitioners. However, I believe that every effort should be made to achieve this goal. If an impasse occurs then CAS could still be performed but without reimbursement.
3. I suspect that a truly high risk patient that is definitively symptomatic from a 50-70% stenosis should be considered for CAS. The problem is that it is often difficult to prove the relationship of the symptoms to these more minor lesions and as such, in an experience of over 1500 CEA’s, I have only performed 3 for such lesions
4. Some patients can simply not be safely treated with a filter. Forcing the physician to try to place one simply to gain reimbursement may result in an increase in complications. I believe most practitioners would always use a filter whenever possible if only for protection against malpractice claims but would not use them when judgment suggests otherwise. I am against tying reimbursement to filter placement.

Thank you for your attention,
Russell H. Samson, MD, FACS, RVT

I believe that the data supports the expanded coverage and the restrictions. I do not believe that it is necessary for a surgeon to assess high risk status. The surgeons have not been the ones to risk statify the patients previously. It has always been the Neurologists, internists, and cardiologists that risk stratify patients. There is just as much chance that the interventionalist will favor stenting as there is the vascular surgeon will favor carotid endarterectomy. I have already seen an increased propensity to proceed to CEA by some of our surgeons, in the high risk patient. I believe that the stenting interventionalist is just as capable of assigning risk status as the surgeon. It is unnecessary for the patient to wait wks and pay for yet another consultation for a procedure that is done in different ways by different specialists. I would recomend mandating a check-list that must be completed on every patient, detailing the accepted reasons for high risk status for CEA.

Ajay Virmani

The notion of required that a CEA credentialled surgeon determine the patient's high risk status for appropriateness for reimbursement for carotic stenting is flawed. While a vascular surgeon may be in the best position to determine the technical issues involving CEA; the patient's cardiac, pulmonary and non-carotid vascular risk are best determined by a cardiologist. In practice, it is cardiologist who are called upon to "clear" patients for vascular surgery. The risk of coronary events (The mechanism of most adverse events in the SAPPHIRE trial and the primary cause of death in surgical trials such as NASCET) are best monitored by a cardiologist and not by a CEA surgeon. The appropriate decision

for choice of therapy is a complex one and thoughtful and reasonable physicians should not be held hostage by reimbursement regulations and a potentially isolated perspective of one group or another.

Andrew C. Eisenhauer MD
Director, Interventional Cardiovascular Medicine Service
Brigham and Women's Hospital
Assistant Professor of Medicine
Harvard Medical School

I am a vascular surgeon who performes both CEA and CAS. I agree with the proposed guidelines. The data are difficult to interpret, however, the octagenarian population appears to be high risk for CAS. I also agree that surgeons should be evaluating the patients for "high risk". As the devices improve, this may change, however there should be continued surveillence of this procedure.

Dear Sir or Madam:

The determination whether the patient is high risk of not for CEA can be made by any specialist in Cardiovascular diseases. It is a clinical decision based on the patient's medical condition. The necessity to have privileges to perform CEA would exclude many Cardiovascular specialists who are competent in endovascular (carotid) procedures without any significant addition to the merit of risk determination. As a matter of fact, such Cardiovascular specialists who may be more familiar with the patient's cardiac or general medical condition are probably more reliable in determining the patient's risk. I would propose to eliminate the condition that stipulates that the surgeon performing the consultation that determines high risk status be properly credentialed to perform CEA. Thank you.

Sincerely,

Joseph Salloum, MD

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February 26, 2007

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Response to the Proposed Decision Memo for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R3)

Dear Dr. Phurrough:

The Society of Interventional Radiology (SIR), on behalf of its 4,300 members who practice vascular and interventional radiology, appreciates the opportunity to comment on the Proposed Decision Memo for PTA of the Carotid Artery Concurrent with Stenting. Our comments will focus on the following proposed revisions to the existing NCD:

1. payment for asymptomatic high surgical risk patients with stenosis > 80%
2. an embolic protection device (EPD) must be used
3. new definitions of high surgical risk
4. the surgeon who confirms high surgical risk must perform carotid endarterectomy
5. exclusion for patients > age 80 unless part of an approved trial

We will also comment on a proposal from SCAI to create an accreditation program.

1. **Payment for asymptomatic high surgical risk patients with stenosis > 80%**

   SIR supports the expansion of payment for asymptomatic high surgical risk patients provided that there is net patient benefit. Net patient benefit has been defined by the American Heart Association (AHA) [1] and the American Academy of Neurology (AAN) [2] as being able to perform carotid revascularization with a perioperative (30 day) combined stroke and death rate of ≤ 3% in patients with an expected survival of at least 5 years. This threshold was derived from the natural history of untreated carotid stenosis in asymptomatic patients with stenosis > 60% diameter (about 2%/year stroke), the benefit from revascularization (stroke risk reduced to about

1%/year), and the need for patients as a group to live long enough to benefit over time from this reduced annual stroke rate after suffering the immediate increased risk of stroke and death from the revascularization.

SIR believes that the AHA and AAN threshold is also valid for the high surgical risk patients covered by the CMS NCD. Although the AHA and AAN recommendations were not based on high surgical risk, current data indicate that patients at high surgical risk have a similar annual rate of developing a stroke caused by the carotid artery stenosis itself (which would be the only cause of stroke correctable by carotid revascularization), a similar benefit from revascularization, but a higher risk of mortality both from their disease and from carotid revascularization.

Stroke risk vs surgical risk

The ACSRS Study [3, 4] analyzed results from 1,101 patients with an asymptomatic carotid stenosis who were followed for up to 7 years. The annual ipsilateral stroke rate for patients with 82% - 99% stenosis (NASCET measurements) who had a normal serum creatinine and no symptoms of contralateral TIA was only 1%. This is equal to the outcomes expected after successful revascularization and indicates no possibility of benefit from revascularization. Patients with a creatinine > 85 umole/L had an annual stroke rate of 2.2%. Patients with a history of contralateral TIA had an annual stroke rate of 2.6%. These rates are nearly identical to the risk of stroke in asymptomatic medically treated patients with > 60% stenosis studied in the ACAS [5] and ACST [6] trials. These data from ACSRS confirm the findings from ACAS and ACST that higher degrees of stenosis do not, in general, produce a higher risk of stroke. Therefore, the presence of an asymptomatic > 80% stenosis should not be considered a high stroke risk category. These data also confirm that patients at high surgical risk are not necessarily at high risk for stroke without revascularization. There was no significant difference in annual ipsilateral stroke rate between patients in the low vs high cardiovascular risk groups (each about 2%/year). Only those patients in ACSRS with > 82% stenosis and with both elevated creatinine and history of contralateral TIA had an annual stroke rate above the natural history of stroke rates used by AHA for their recommendations. In that subgroup, the annual stroke rate was 6.3% [3]. It is unknown if this increased stroke rate was due to the carotid stenosis or due to small vessel disease. The latter would not be improved with carotid revascularization.

Mortality in high surgical risk patients

In ACSRS there was a marked difference in mortality between patients with low and high cardiovascular risk. The annual mortality rate (as opposed to stroke rate) of low vs high cardiovascular risk was 3% vs 9.5% [4], or about 50% mortality at 5 years. Similarly, the 3 year data from SAPPHIRE show a mortality in the CAS group of 20%, which extrapolates to 35% at 5 years. The higher mortality rate in this high surgical risk group decreases or even erases the benefit that this group might possibly receive from CAS even if this group could be treated with acceptable outcomes.

Increased mortality from age > 75 even without medical comorbidities was the major factor in there being no significant benefit from endarterectomy in ACST.

Benefit of CAS in high surgical risk patients

The criteria of elevated creatinine and contralateral TIA that were associated with increased risk of ipsilateral stroke in ACSRS were not evaluated in the high risk carotid stent trials (for example, in ARCHeR [7] only 3% of patients had dialysis dependent renal failure). Therefore, there is no information on the stroke prevention benefits from stenting this population. It is unknown if CAS has higher morbidity in this group or if these patients survive long enough to benefit from CAS. For the currently defined high surgical risk population the long term benefit from CAS beyond the perioperative period is similar to CEA with post revascularization risk of stroke of about 1-1.5%/year reported in ARCHeR and SAPPHIRE [7, 8]. Given a risk of ipsilateral stroke without revascularization in these patients of about 2%, the reduction in risk is only about 1%/year. Hence the need to survive for at least 5 years to offset the initial morbidity from the procedure before net patient benefit occurs. A perioperative risk > 3% produces net patient harm, particularly when 1/3 to 1/2 of treated patients will not survive 5 years.

Therefore, current information indicates that the natural history of stroke occurrence and benefit from revascularization are comparable in the high and average surgical risk populations, and the threshold of 3% perioperative stroke and death that distinguishes between net patient benefit and net patient harm is applicable to the high surgical risk population. This 3% threshold has, in fact, been adopted by a multispecialty Italian Consensus document on carotid stenting [9].

SIR believes that the 3% threshold for perioperative stroke/death for CAS is not only essential to preserve net patient benefit (rather than harm), but is also achievable with current technology by well trained interventionalists. Such outcomes have been achieved by Chaer et al [10], Halabi et al [11] Verzini et al [12], Stanziale et al [13] (for age < 80), CaRESS [14], Hofmann [15] and are very close for CREST (for age < 80) [16]. This threshold has not been uniformly achieved in other large trials and registries such as CAPTURE (for age <80) [17], SAPPHIRE, or ARCHeR. Therefore, it cannot be assumed that acceptable outcomes will be uniformly achieved as CAS is more widely performed under the revised NCD.

SIR therefore suggests that reimbursement be provided for treating high surgical risk asymptomatic patients with carotid stenosis > 80% only if the outcomes can be documented as ≤ 3% stroke and death. For similar reasons, we believe that the historical benchmarks for carotid revascularization for symptomatic patients should also apply to high surgical risk patients treated with CAS (≤ 6% stroke/death). We suggest that data on outcomes be obtained by requiring participation in one of the national carotid stent registries and that accurate neurologic assessment of the patient pre and post CAS be performed by staff certified in the use of the NIH Stroke Scale. We understand that linking payment to outcomes and mandating participation in

national registries is not part of the current NCD and that CMS is, therefore, currently not able legally to include these requirements. However, since CMS is currently revising the NCD we suggest adding these criteria to the revisions. This would allow CAS to be performed with some assurance that net patient benefit is present.

2. An embolic protection device must be used

Based on a lower procedural stroke rate in several studies, most notably the EVA-3s study [18] in which the stroke rate in patients treated without an embolic protection device (EPD) was three times greater than when such a device was used, CMS is now stating that not only must an EPD be attempted but it must be successfully placed prior to stent placement in order for the procedure to qualify for reimbursement. SIR has a concern that this requirement is too restrictive and may in fact lead to greater patient harm than allowing EPD use to be optional if technically difficult. The evidence supporting the additional benefit is suggestive but not definitive. While EVA-3S did find a marked benefit with use of EPD, SPACE [19] found no difference. In the three ARCHeR registries, the stroke rate was actually lower in the first registry that did not include use of EPD. Most of us would consider that use of an EPD passes the "parachute" test that one doesn't jump from an airplane without a parachute even in the absence of proof of effectiveness, and we are convinced that the debris frequently captured in filters is best not allowed to reach the brain. But the technical difficulty in placing an EPD in every patient may result in an increased risk of stroke if the operator feels required to place the device. The difficulty encountered in placing the device will occur only after the case is well underway making it difficult to stop and lose reimbursement for the procedure. Yet, if the operator decides that EPD placement is too risky and proceeds without EPD the procedure will also be without reimbursement. As a consequence, all patients may be required to sign an Advanced Beneficiary Notice (ABN) that obligates them to pay for the procedure if not covered by insurance, which will be alarming to patients and add significant stress for the patient and family considering this procedure. The most likely scenario is that the operating physician will choose to try harder to place the EPD, which may well increase the risk of stroke from the procedure. SIR does not believe that there is a potential for abuse if EPD placement is allowed to be optional if the attempt to place it fails. We believe that physicians will use good judgment to abort those procedures with stenosis believed to be at high risk of embolization (ulceration and irregular plaque) and continue with those procedures at lower risk (smooth stenosis, such as post endarterectomy restenosis). Furthermore, if physicians and facilities are required to achieve outcomes of $\leq$ 3% for asymptomatic and $\leq$ 6% for symptomatic patients any increased stroke risk from not using an EPD or from attempting to use one when the anatomy is challenging will be apparent and physicians will alter their behavior.

3. Definitions of high surgical risk

The revised definitions of high surgical risk include a history of myocardial infarction, a positive stress test, and clinically significant cardiac disease. SIR

believes that these new criteria are insufficiently specific, will allow many patients not previously considered to be high surgical risk (and, therefore, not previously studied in high risk trials) to be labeled high surgical risk in routine clinical practice, and are susceptible to abuse. We believe that the prior definitions of significant cardiac disease defined as CHF NYHA class III/IV or unstable angina (Canadian Cardiovascular Society class III/IV) or ejection fraction < 30% are specific and sufficient. We suggest that a history of myocardial infarction should be specific for when the infarction occurred, such as within the past month as used in ARCHeR. These criteria were, in fact, adopted by Cremonesi et al in the Italian multispecialty recommendations. We suggest that a positive stress test not be considered a high risk criterion. False positive stress tests are frequent, particularly if unaccompanied by cardiac perfusion imaging or echocardiography, and even small abnormalities would qualify the patient as high risk. The ambiguity, lack of specificity, and potential for abuse raise the potential that large numbers of patients now considered at average risk for surgery and for whom there is insufficient evidence of net patient benefit from CAS will now be treated with CAS with reimbursement by CMS. In addition, the ability to shift average risk patients into the high risk category using nonspecific definitions will make it extremely difficult to enroll average risk patients into randomized trials.

4. **The surgeon who confirms high surgical risk must perform carotid endarterectomy**

It appears that a surgeon is being used as a gatekeeper to confirm that a patient labeled as high risk for carotid endarterectomy is truly high risk. It does make sense that the surgeon used for this confirmation performs endarterectomy, and such a surgical opinion is particularly important for the evaluation of patients with anatomic reasons to be considered high risk. A surgeon who performs CEA may determine that a patient is at high-risk for surgery despite not meeting criteria that CMS defines, and in those cases, the determination by the surgeon could stand in lieu of meeting the specific criteria outlined in the NCD. However, surgical confirmation is difficult to enforce and has not currently been enforced. It seems that the need for such confirmation is a reflection of the ambiguity and lack of specificity of the high risk criteria. SIR believes that it is preferable to have clear, specific, and unambiguous criteria for high risk such that independent second opinion confirmation is not necessary. For this reason SIR suggests that the criteria of clinically significant cardiac disease and positive stress test be eliminated and that myocardial infarction be specified to be within the past month.

5. **Exclusion for patients > age 80 unless part of an approved trial**

SIR shares the concern of CMS that complications of CAS have been poor in octogenarians. It is very possible that the poor outcomes are due to tortuous anatomy rather than to age and better patient selection may allow octogenarians to receive CAS with fewer complications. This remains to be proven and SIR supports the continued study of these patients with reimbursement as part of approved trials, such

as the ongoing CREST trial. Such patients would still need to have a life expectancy of at least 5 years to benefit from CAS even if complication rates are low.

6. **Proposal from SCAI to create an accreditation program**

SIR agrees that an accreditation program is useful. It would provide a simple mechanism for instituting the suggested outcomes benchmarks of ≤ 3% stroke/death for asymptomatic patients and ≤ 6% stroke/death for symptomatic patients. However, the SCAI proposal has some problems.

First, it will be necessary that an accreditation program be formed with the cooperation and collaboration of all of the stakeholder societies. While the SCAI proposal states that SIR was a collaborator on their proposal, this is not the case. We believe that other societies such as SVS who are listed as collaborators also did not participate in creating the SCAI proposal. Multiple societies could form their own accreditation programs, but we believe the ideal would be for accreditation to be performed by an independent or multispecialty entity.

Second, SIR strongly disagrees with the proposed benchmarks for outcomes. SCAI proposes that benchmarks be set according to the average results that have been published and that a 6% 30 day stroke/death outcome for asymptomatic patients is acceptable for accreditation. This is double the threshold of the AHA and AAN and would confer net patient harm rather than benefit at a huge monetary cost to society. As noted above, SIR believes that outcomes must be set at the threshold that ensures net patient benefit, not the threshold that is the upper limit of the average result. Cremonesi et al in the Italian multispecialty consensus statement argue that stroke/death must be no higher than the upper acceptable limit rather than set according to a central estimate. They require for symptomatic patients a stroke/death of ≤ 6% and disabling stroke/death of ≤ 2%. For asymptomatic patients they require a stroke/death of ≤ 3% and disabling stroke/death of ≤ 1%.

Third, we believe that there must be a mechanism to distinguish facility outcomes from outcomes by individual physicians. A single physician with a high stroke/death rate can give the entire facility overall unacceptable outcomes. While this does give the facility the incentive to closely monitor physician outcomes it also may be a disincentive for a facility to allow a new operator to perform CAS.

Summary:

SIR suggests the following revisions to the CAS revised NCD:

1. Net patient benefit for asymptomatic <age 80 high surgical risk patients with ≥ 80% diameter stenosis be assured by requiring
    a. 30 day stroke/death ≤ 3%.
    b. participation in one of the national CAS registries.

2. Net patient benefit for symptomatic < age 80 high surgical risk patients with ≥ 70% diameter stenosis be assured by requiring
    a. 30 day stroke/death ≤ 6%.
    b. participation in one of the national CAS registries.
3. Use of an EPD must be attempted but is not required if, in the opinion of the operating physician, the use would be technically difficult and increase the risk of procedural stroke.
4. The definitions of high surgical risk should be very specific
    a. The term "clinically significant" cardiac disease should be eliminated.
    b. Abnormal stress test should be eliminated.
    c. Myocardial infarction should be within the past month.
5. Confirmation of high surgical risk should require confirmation by a surgeon who performs endarterectomy unless the high surgical risk criteria are made very specific.
6. Facility accreditation outside of the accreditation currently required by CMS should be created with multispecialty collaboration and incorporate the outcome benchmarks listed in suggestions #1 and #2.

Thank you again for the opportunity to submit these comments. If we can provide any additional information or if you have any questions, please do not hesitate to contact me at (317) 338-9846 or Tricia McClenny, SIR's Associate Executive Director, at (703) 691-1805 or tricia@sirweb.org.

Sincerely,

Katharine L. Krol, MD

Katharine Krol, MD
President, SIR

cc: Sarah McClain, MHS
Marcel Salive, MD, MPH
David Sacks, MD
Peter B. Lauer, CAE
Tricia McClenny

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January 25, 2007

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Phurrough,

Massachusetts General Hospital would like to provide comments on CMS requirements for data submission on carotid stenting procedures.

We support the proposed change in the data collection requirements associated with the national coverage decision for carotid stenting. Under the proposal, hospitals would submit data on all high-risk carotid stenting patient cases via CMS-approved data registries. The submission of data via a professional society registry or approved hospital registry would satisfy CMS requirements related to both certification and coverage. The Massachusetts General Hospital carotid database is a comprehensive database designed by a multispecialty physician committee with input from experienced information technology experts, merging the best of the SVS and CARE registries. All high-risk patients would be covered as long as data were submitted to CMS via a registry making enrollment in manufacturer sponsored FDA post-approval trials no longer necessary. This same data would support hospital certification requirements, thereby improving efficiency.

This proposal streamlines data collection and reporting. Multiple overlapping data reporting methods i.e. 1) FDA post-approval studies, 2) societal registries and 3) the CMS certification system would be replaced with a CMS-approved societal data registry. The submission of data on ALL high risk surgical patients to CMS, via approved registries would better inform treatment decisions and improve the quality of care for our patients with carotid artery disease.

Sincerely,

Christopher Kwolek, MD
Co-Chair, MGH Vascular Center
Q/A & Database Committee

Karen Furie, MD
Co-Chair, MGH Vascular Center
Q/A & Database Committee

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The Society for Vascular Medicine and Biology

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January 23, 2007

Steve Phurrough, M.D., M.P.A.
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Phurrough:

The Society for Vascular Medicine and Biology (SVMB) would like to provide comments on CMS requirements for data submission on carotid stenting procedures.

The SVMB supports the proposed change in the data collection requirements associated with the national coverage decision for carotid stenting. Under the proposal, hospitals would submit data on all high-risk carotid stenting patient cases via CMS-approved physician specialty society data registries. The submission of data via a societal registry would satisfy CMS requirements related to both certification and coverage. All high-risk patients would be covered as long as data were submitted to CMS via a registry making enrollment in manufacturer-sponsored FDA post-approval trials no longer necessary. This same data would support hospital certification requirements, thereby improving efficiency.

This proposal streamlines data collection and reporting. Multiple overlapping data reporting methods, *i.e.* 1) FDA post-approval studies, 2) societal registries, and 3) the CMS certification system are replaced with a CMS-approved societal data registry. The submission of data on <u>all</u> high surgical patients to CMS, via societal registries would better inform treatment decisions and improve the quality of care for our patients with carotid artery disease.

Sincerely,

John P. Cooke, M.D., Ph.D.
President, Society for Vascular Medicine and Biology

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January 30, 2007

Steve Phurrough, M.D., M.P.A.
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Baltimore, MD 21244

Dear Dr. Phurrough,

New York-Presbyterian Hospital would like to provide comments on CMS requirements to submit data on carotid stenting procedures for the purpose of facility certification of the high-risk patient population.

In 2006, New York-Presbyterian Hospital performed a total of 130 Carotid Stent procedures. This specific procedure is performed by several services at the Weill Cornell and Columbia Presbyterian Campuses. These services include: Vascular Surgery, Interventional Cardiology, Interventional Neuro Radiology and Neurosurgery.

We understand that CMS is considering a change in the data collection requirements associated with the national coverage decision for carotid stenting. Under the proposal, hospitals would submit data on all high-risk carotid stent patients to CMS approved physician specialty society registries. The submission of data to a physician society registry would satisfy CMS requirements related to certification. In other words, all patients having a carotid stent procedure would be submitted to a national registry, with hospitals no longer having to submit data directly to CMS for certification, as this role would be shifted to the physician specialty societies.

We support this proposed change in data collection requirements. From an administrative perspective, it would be much more efficient if we could submit data to society registries only instead of through multiple overlapping systems including FDA post-approval studies, society registries and the CMS certification system. In addition, the submission of data on all patients to society registries would facilitate the analysis of outcomes across all patients in order to better inform treatment decisions and improve the quality of care for our patients with carotid artery disease.

Sincerely,

Robert E. Kelly, M.D.

REK:ek

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February 21, 2007

Steve Phurrough MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
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Dr. Phurrough,

Rather then send a comment on the anticipated CMS proposal; we thought we would forward you this editorial that is in its final stages prior to publication. It basically outlines the current status of the asymptomatic patient. It is in keeping with the current CMS proposal with a few commentaries on octogenarians. We feel quite strongly the octogenarians can be done but would necessarily be done in a separate registry with skilled operators. Again, when we surveyed three major European centers as well as three U.S. centers of both high volume and high technical skill operators there was little or no difference in the event rates in octogenarians versus non-octogenarians. The bottom line is operator experience and careful patient selection, two critical criteria that take considerable judgment. We also feel strongly that octogenarians ultimately should be included since they represent the very age group that would benefit from the simplicity of endovascular carotid stenting in a carefully selected subset. The surgical data would suggest that octogenarians have the most to gain in terms of risk reduction and that should be duplicated by endovascular carotid stenting again, in the right environment.

Our experience here in Pittsburgh is internationally recognized and we represent one of the major carotid centers in the U.S.

Sincerely,

Mark Wholey

Mark H. Wholey, MD
Chairman
Pittsburgh Vascular Institute

Item# 02157

UPMC | University of Pittsburgh Medical Center

UPMC Presbyterian Shadyside

Is Carotid Stenting Justified in the Asymptomatic Patient?
Perspectives on indications for CAS

Mark H. Wholey, MD and Joel E. Barbato, MD

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The American Heart Association has published guidelines suggesting that the asymptomatic patient with carotid occlusive disease and a life expectancy of less than five years should not be considered a candidate for interventions, whether endarterectomy or endovascular stenting. However, they also estimate that the cost of stroke-related morbidity will be a staggering $63 billion in the United States for 2007. For patients with a mortality risk of less than 3% and a life expectancy of at least five years, intervention may therefore be desirable. When the surgical risk is 3-5%, a proven indication is controversial but it may be acceptable to proceed when ipsilateral carotid stenosis is greater than 80%, especially if contralateral internal carotid artery occlusion exists.

The assumptions upon which the decisions to treat the asymptomatic patient are founded on landmark studies such as the Asymptomatic Carotid Atherosclerosis Study (ACAS), the Veterans Affairs Cooperative Study (VA), and the Asymptomatic Carotid Surgery Trial (ACST). In total, these trials randomized over 5000 patients to surgical or medical therapy. Overall, these trials demonstrated a 2.9% perioperative stroke and death rate. 75% of the patients currently undergoing carotid endarterectomy and carotid stenting are asymptomatic from their disease. Asymptomatic disease is highly prevalent in the general population and a close correlation exists with other atherosclerotic disease in the coronary and peripheral circulation. Compared with symptomatic stenosis, most available data continues to suggest that asymptomatic carotid artery stenosis is associated with a relatively low risk of ipsilateral stroke. Based on the five year projection, the ACAS data showed that CEA reduced the absolute risk of stroke by 5.9% and the relative risk of stoke and death by 53%. However, the surgical benefit incorporated a very low periprocedural stroke and death rate of only 2.3%

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including arteriographic complications that amounted to 1.2%. Esesentially the benefit of surgical intervention in this patient population is minimized unless the operation is performed by an experienced surgeon with documented complication rates including arteriogram (if required) and the surgery of less than 3%.

Criticisms of the methodology of these studies (on which our treatment of asymptomatic patients is based) makes their interpretation difficult. ACAS was based on patients with stenoses of 60% or more while essentially all of the high-risk CAS registries require an 80% degree of stenosis for enrollment. Most of these patients in this "high surgical risk" category would have been excluded from either NASCET or ACAS. Criticism of the CAS registries has occurred in that 75% of the patients were asymptomatic while only 25% were symptomatic and furthermore 25-30% of all the patients enrolled in the registries including the Sapphire Trial had a history of prior CEA. It is fairly well-established that these patients with prior CEA respond satisfactorily to endovascular stenting and in the incidence of embolic events is considerably lower which may skew the data in favor of CAS. For example, in the Archer Trial the periprocedural stroke rate with stenting in patients with prior endarterectomy was 0.7% while a literature review identified a 7% periprocedural stroke rate with redo endarterectomy. What was quite significant in the registries was the *major* stroke event rate never exceeded 2% and in fact most were in the range of 1.3-1.5% with Sapphire reporting no major strokes in the randomized arm.

Understanding the intracranial circulation and stratification of these risk factors is essential before assigning the asymptomatic patient with a high-grade stenotic lesion to best medical management. For example, if ipsilateral carotid artery occlusive disease exists and there is absence of a communicating Circle of Willis, this patient is placed at potentially unreasonable risk if left untreated. This is also true if there is basilar artery occlusive disease and collateralization to the basilar occurs from the posterior communicating artery in the ipsilateral carotid artery. Surprisingly these intracranial risk factors are never discussed in the analysis of the justification of these asymptomatic patients undergoing intervention. Furthermore we know from the natural progression of occlusive disease that occurs in the renal, coronary and peripheral circulation that high grade lesions can go on to total obstruction in approximately 17% of patients. We have seen this repeatedly in patients with high-grade carotid artery lesions awaiting endovascular stenting that subsequently present with occlusion but remain asymptomatic secondary to the fact that there is often excellent collateralization. The 3% event rate in the asymptomatic population is an achievable goal if well developed guidelines are followed. For example, in the Capture trial in the asymptomatic population with exclusion of octogenarians, an event rate of 3.2% was described. The 3% threshold was also achieved in the CaRESS and CABERNET trials. This number is achievable but it will necesasarily be done under rigid guidelines.

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In the asymptomatic patients there is also controversy over whether the degree of stenosis is relevant as a stroke risk predictor. The literature would suggest that stenosis in the 50-70% range may be best managed conservatively but in the 80-90% and 90-99% range, the annualized stroke event rate in the "conservatively" managed patients could be as high as 8%. The ACST Trials demonstrated that the stroke rate for medically treated asymptomatic patients, whether 60-79% or 80-99%, was of little or no difference with a five year stroke rate of roughly 10%. Consequently there is significant controversy over the degree of stenosis as being an indicator for intervention. For the patient with 80-99% stenosis, there is obviously a question of judgment that would favor intervention based on the natural history of preocclusive lesions in other vascular compartments. In both NASCET in the 60-69% group of patients and the entire ACAS study there was no benefit shown for endarterectomy for women. This becomes even more substantial when recognizing the procedural risk was less than 2.5% in ACAS and still produced no benefit for women. The ACST trial included all strokes including contralateral events and vertebrobasilar strokes. If the ACST analysis was limited to ipsilateral strokes only, the absolute benefit would be even further reduced. This is a fact that is often ignored.

Based on the existing data it would appear that carotid stenting or surgery may be more desirable than best medical management in the high–risk critical stenosis involving the carotid artery. All of this assumes that in the asymptomatic population the periprocedural stroke risk will not exceed 3% and in the symptomatic subset will not exceed 6%. Data from the German Registry of over 2000 patients had an event rate in the symptomatic syubset of 939 patient of major stroke 1.6% and minor storkes of 1.1% for a combined total of 2.7%. In the ACAS trial, patients with 60-69% lesions had 11.4% 5 year stroke rate while 70-79% had 6.7% and 80-99% had 3.7%. Obviously the degree of stenosis was not a strong predictor in the ACAS trial. In the ACST trial 60-79% and 80-99% had the identical 9.5% stroke and death rate in five years. The 30 day stroke and death rate in Archer was 6.9%. In ACST trial the 5 year risk of stroke was 3.8% with immediate endarterctomy and 11% when the treatment was deferred until stenosis advanced.

What has been established is that carotid stenting in the high-risk subset of patients is at least the equivalent of carotid endarectomy and in several parameters better. This was especially true in the diabetic subset of the Sapphire trial where the MAE (major adverse events) was 4.5% in the stenting arm and an alarming 24% in the endarterectomy arm. Although the asymptomatic carotid indication is being fiercely argued, it is inconceivable that we would send a patient home in spite of a

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sedentary existence with occlusive disease of the left main coronary artery. Nor would we deny the patient with renal vascular hypertension and a solitary kidney with high grade stenosis a renal artery stent or for that matter the patient with lifestyle limiting claudication a potentially therapeutic intervention. Why then would we consider sending a patient home with critical stenosis of a dominant hemisphere internal carotid with a 95% ulcerated stenosis? Obviously in these situations patient selection becomes paramount. This is also closely coupled to operator experience. To achieve the 3% rate in this subset of patient there may be an obvious bias in patient selection. Patients with complex atherosclerotic Type III or IV aortic arches, tortuosity and atherosclerotic changes in the proximal carotid or the suspicion of clot at the target lesion site as well as lengthy tandem lesions are all risk factors that may be excluded from stenting. More recently, we have introduced intravascular ultrasound with virtual histology (IVUS-VH) for lesion analysis prior to stenting. If on VH the plaque composition is heavily weighted to necrotic core with only a thin fibrous cap, we would defer stenting and send the patient for CEA. To eliminate this selection bias, a randomized clinical trial would potentially solve these issues. Randomization and patient and physician bias present problems in that these trials rarely finish in a timely fashion as CREST demonstrates, with only slightly over half of the 2500 intended participants recruited over five years. Furthermore, these device trials are in continual evolution as the generation of devices presently being used becomes obsolete at the completion of the trial. Carotid stenting, for example, is only in its first and second generation of designs. We already know the limitation of the distal protection devices and the potential need for coupling the distal filters with flow reversal systems in order to capture the particles that are 50 microns or less.

Asymptomatic octogenarians also present their own separate issues in that the Crest trial reports 12% periprocedural event rate in the octogenarians with only 2.5% in the under-80 age group. Stanziale also reported an 8.5% event rate in octogenarians and most recently the Capture data suggest an unacceptable 13% in the asymptomatic octogenarian. 20-28% of the patients enrolled in Capture and in Sapphire were in fact over 80 years of age. The octogenarian reports, however, are generally based on small numbers and are not consistent with surgical data. Miller reported 360 procedures in octogenarians with a nonsignificant 1.1% stroke rate versus 0.8% in non-octogenarians. When we surveyed five high volume centers with experienced operators, the stroke event rate was not greater than 3.7% with no significant difference between those patients over or under the age of 80. In our most recent 200 carotid stents of which 63 were octogenarians, there was only one major stroke. These data call into question the notion that octogenarians present a prohibitive procedural risk.

Carotid angioplasty and stenting is clearly a technology that is here to stay. It is also clear that the current application of the technology has overstepped many of its current limitations. What is needed is a better understanding of those patients

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for whom carotid stenting is the preferred intervention over endarterectomy. With improvements in stent and distal protection technology, there will undoubtedly be significant changes in the periprocedural event rates which will swing the balance of benefit toward the side of CAS in certain patient subsets. Furthermore, research into which lesions are truly high-risk lesions (with the use of virtual histology, for instance) will also contribute to our ability to triage patients into the appropriate therapy. If well-designed studies cannot be performed to demonstrate this benefit, however, we will continue to exist in the "wild west" of medical practice with inexperienced operators applying this technology to patients inappropriately, further propagating the bad press that has recently soured many on this technology. In the meantime, operators must be held to a rigid standard of 3% periprocedural event rate in the asymptomatic patient and 6% in the symptomatic patient until a more elegant understanding of patient and technology selection can be demonstrated.