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March 3, 2007

Sarah McClain, MHS
Joseph Chin, MD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CAG-00085R3
P.O. Box 8014
Baltimore, MD 21244-8014

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 $\geq 50\%$ and $\leq 99\%$ 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 $\geq 50\%$ and $\leq 99\%$ 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 ($\leq 6\%$ 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 $\geq 50\%$ and $\leq 99\%$. 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 $\geq 50\%$ and $\leq 99\%$. 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 SAPPHERE, 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 202.375.6392, or by e-mail at ssantivi@acc.org.

Sincerely,



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



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



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

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