



The Society for Cardiovascular
Angiography and Interventions



AMERICAN
COLLEGE of
CARDIOLOGY



Society for
Vascular Medicine



August 29, 2008

VIA Electronic Submission

Steve Phurrough, M.D., M.P.A.
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Dear Dr. Phurrough:

The Society for Cardiovascular Angiography and Interventions, the American College of Cardiology, the Society for Vascular Medicine and the Society of Vascular Interventional Neurology are responding to the CMS proposed decision memorandum (CAG-000885R6) denying our request for an expansion of coverage for carotid artery stenting (CAS) *in patients who are at increased perioperative risk for carotid endarterectomy (CEA) complications due to defined anatomic factors and who have either symptomatic carotid artery stenosis of 50-69% or asymptomatic carotid artery stenosis of $\geq 80\%$* . Our request to CMS for expanding Medicare coverage to this population was motivated by an appreciation of the compelling scientific evidence that revascularization with CEA prevents stroke compared to medical therapy and that, in patients at high risk for CEA, revascularization with CAS is a safe and efficacious alternative. Without CMS approval of coverage for this unfortunate patient subset, only those Medicare beneficiaries who are able to pay out of pocket for this service will be allowed to avail themselves of this treatment.

HIGH SURGICAL RISK PATIENTS

In Section VII. A. of the memorandum, the evidence is discussed. We are concerned that CMS has misunderstood the issue of unfavorable anatomic features and erred in asking whether anatomic factors would make CEA contraindicated. It is not necessary that CEA be contraindicated in order to make the CEA procedure more difficult or higher in risk. High surgical risk CEA patients, of which the anatomic subgroup is a minority (20% to 40%) compared to the larger group with unfavorable medical comorbidities, provides one of the largest populations of vascular patients ever studied. There is compelling evidence in patients at increased CEA risk from a randomized controlled trial¹ and thousands of patients treated in highly structured FDA device approval trials and clinical registries²⁻⁸ that have unequivocally shown that CAS is not inferior to CEA. In patients with predefined medical comorbidities and adverse anatomic features, CEA need not be contraindicated to warrant consideration of CAS as a reasonable therapeutic alternative. CMS should not require that CAS be superior to CEA to consider it a valid treatment option. The decision to proceed with CAS or CEA is a risk to benefit assessment to be considered by the patient, their family and their treating physician. A similar corollary is a patient who

needs coronary revascularization, and is deemed to be at high risk for coronary artery bypass graft surgery (i.e., repeat coronary surgical revascularization, lack of suitable conduit, etc., severe obstructive lung disease). This patient is appropriately offered percutaneous coronary revascularization. Certainly, the data generated in support of carotid artery stent placement exceeds any similar data for coronary artery disease in quality and quantity.

CMS asks if there is specific evidence that treatment with CAS for the subgroup of patients with high surgical risk anatomic factors improves health outcomes. Again, the anatomic high surgical risk group comprises a minority (20% to 30%) of all patients who are at increased surgical risk for carotid revascularization. There is absolutely no question, based upon the 1 and 3 year follow-up evidence of the randomized clinical trial and the FDA device approval trials that CAS, in patients at increased risk for perioperative surgical complications offers comparable, if not superior outcomes to those obtained with CEA^{2,3,5-11}. The patient group most in need of coverage because of the lack of alternative therapies--the anatomic high risk group--is too small to have served as the focus of any single clinical trial and this should not be cause for rejecting the reasonable request for coverage expansion. The purpose of limiting the requested expansion to the smaller subset of high risk anatomic features is reasonable and efficacious. While medical comorbidities certainly increase the risk of surgical procedures and make some patients unattractive surgical candidates, they do not prevent surgery in many cases. However, unfavorable anatomic features, a hostile neck, or a high cervical or low intrathoracic lesion, are much more difficult for the surgeon to overcome and may prevent needed carotid revascularization. It is specifically for this patient subset that the limited request for extending CMS coverage was made. Without expanded coverage for this subset, Medicare-covered patients who cannot afford to pay fee for service will be denied this safe and effective therapeutic option and may be denied any revascularization.

METHODOLOGICAL CONCERNS

In Section VII.B.2. we take issue with the BlueCross BlueShield (BCBS) technology assessment and believe its findings are self-serving and biased against payment for new procedures. The BCBS's direct and major conflict of interest should make any governmental organization, but particularly CMS, wary of adopting the TEC findings. It is difficult for a reasonable person to read the body of literature that has been collected specifically for high surgical risk CEA patients and not conclude that CAS is a safe and effective option, if not the *preferred* treatment in suitable candidates. In the SAPPHIRE trial, in which independent adjudication of neurologic complications at 24 hours post procedure was assessed, the primary endpoint at one-year demonstrated that CAS was not inferior compared to CEA (ARR 7.9%, 95% CI -16.4% to 0.7%, P = 0.004 for non-inferiority)¹. Importantly, outcomes from the real-world post-FDA IDE post marketing studies continue to show more favorable outcomes⁹. These favorable outcomes have been confirmed in multiple with FDA-sponsored prospective multicenter trials, resulting in FDA device approvals based upon the safety and efficacy of CAS in high surgical risk patients.

CMS creates confusion by mixing non-high risk trials, and by citing surgical trials with endpoints that have not been independently adjudicated. All the CAS trials cited and published have benefited from a robust methodology requiring independent assessment and adjudication of neurologic complications. Few CEA trials include the rigor of independent neurologic examination. When outcomes are compared, CEA has the advantage of potentially under-reporting outcomes, which is why the SAPPHIRE randomized data is so very important. SAPPHIRE is the only direct comparison, the only randomized trial, that has been performed in this population and it demonstrated non-inferiority of CAS compared to CEA. Multiple other non-randomized trials with independent neurologic adjudication of outcomes are consistent with SAPPHIRE's outcomes and strengthen our confidence in the favorable result for CAS.

Isolated surgical reports suffer from excessive heterogeneity for outcome reporting, and therefore cannot be considered valid comparators¹².

COVERAGE OF OCTAGENARIANS

Regarding evidence on CAS in patients greater than 80 years, two manuscripts published this year, yet not considered in the CMS memorandum describe safe and effective CAS in the very elderly and report excellent outcomes for ≥ 80 year-old patients when properly selected and treated by experienced clinicians^{13, 14}. In Section VII.B.5. the reference to the U.S. Preventive Services Task Force (USPTF) is irrelevant. The data discussed by USPTF does not apply to the population (high surgical risk) under consideration for the expansion of this NCD. This type of data-mixing raises concerns regarding CMS' capacity to provide balanced comparison of homogeneous patient subgroups in a non-biased fashion.

DATA REGISTRIES

We are also concerned that CMS's current data collection requirements are not sufficiently robust to afford CMS with valid evidence to inform the coverage determination process. CMS has previously defined the facility and reporting requirements, which must be in place at any hospital offering CAS as a condition for payment for procedures performed on Medicare patients. These requirements include, among other aspects, that facilities with operators performing CAS must provide proper imaging equipment, ongoing cardiovascular monitoring during CAS, a formal credentialing process, and ongoing quality assurance (QA). In addition, hospitals are required to collect basic data regarding every CAS case performed at the facility, and submit those cumulative data to CMS on bi-annual basis in order to re-qualify for reimbursement. Furthermore these are self-reported and are not associated with any validation effort which may compromise their accuracy.

The data elements required for submission are mainly administrative; outcomes data are limited to the incidence of stroke and death, and there are no stipulations regarding objective/independent neurologic assessment or requirements (e.g. auditing) to confirm the completeness or accuracy of the reporting. Thus, the data are of very limited value in tracking the relevant outcomes from CAS at any given facility, and are even more limited when used to compare outcomes across facilities (e.g. for benchmarking performance and outcomes). We welcome the opportunity to discuss use of formal CAS registries by all facilities approved by CMS to perform CAS. At CMS's convenience, we would seek a meeting between agency staff and physicians representing the CAS registries to discuss these issues further and to explore new opportunities for agency use of these clinically relevant data elements.

FACILITY ACCREDITATION

We continue to be concerned by CMS's self accreditation option for facilities performing carotid stenting. An appropriate accreditation program could ensure that registry data is used effectively to improve the quality of care. Unfortunately, CMS's free self-accreditation process makes it untenable to establish a more robust and viable accreditation program. If CMS would truly like to encourage external accreditation program(s), SCAI, along with potential partners would welcome the opportunity to discuss developing such accreditation program(s).

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CONCLUSION

We urge CMS to review the data carefully and to recognize that published studies demonstrate the safety and efficacy of CAS as a viable therapeutic option for patients at high risk for surgery due to anatomic factors. Allowing access to this technology for an important subset of Medicare patients is critical to their receiving optimal care. We look forward to the agency's final decision on this coverage determination. We also wish to acknowledge the efforts of Kenneth Rosenfield, M.D., FSCAI and Christopher White, M.D., FACC, FSCAI who are the primary authors of this communication.


Respectfully submitted,



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