SOCIETY FOR VASCULAR SURGERY

June 4, 2008

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

RE: Draft Decision Memo for Carotid Artery Stenting CAG-00085R6

Dear Dr. Phurrough:

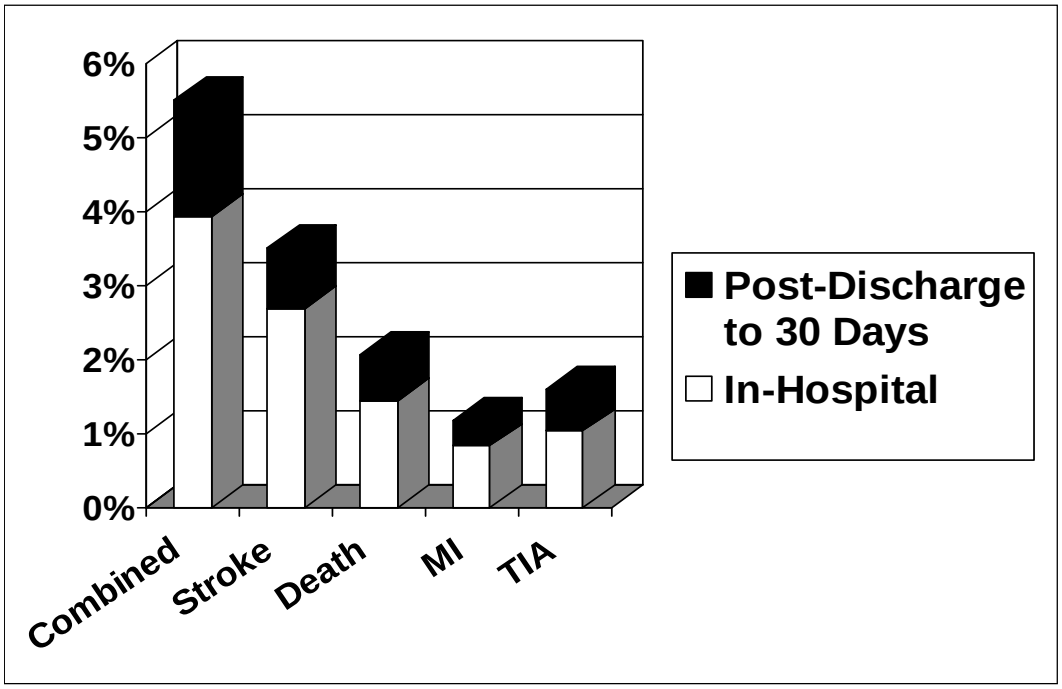
On March 2, 2008 the Society for Vascular Surgery (SVS) submitted comments regarding re-consideration of the Medicare National Coverage Policy for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting (CAG-00085R6, dated February 1, 2008). This letter represents additional comments and two specific requests regarding carotid artery stent (CAS) data collection.

The SVS initiated the first specialty society-sponsored carotid stent registry ("Vascular Registry" or "VR") that began enrolling patients July 11, 2005. To the current time 73 facilities representing 585 providers from 8 medical and surgical specialties in 32 states have entered data regarding carotid stents and carotid endarterectomies in the Vascular Registry. While the VR was organized by SVS, it has been endorsed by the Society for Interventional Radiology (SIR), and as noted, a wide variety of providers enter carotid procedures. SVS is very pleased with the results of this effort because detailed real-

world data, now being analyzed, can aid in determining the subsets of patients who will benefit most from carotid artery stenting. We are also aware that at least one other society sponsored registry, (NCDR CARE), has initiated operation and is collecting CAS data. We are concerned that the CMS-required CAS data elements do not take full advantage of the meaningful opportunity brought about by the NCD mandate to report outcomes because those elements lack sufficient detail to perform a thorough risk-adjusted analysis. In contrast, the robust nature of the specialty-society CAS registries allows opportunity to provide evidence-based answers that will benefit Medicare patients.

Following recent conversations with CMS CAG reinforcing the Agency statement in the April 2007 (CAG 00085R3) document that “facilities may experience advantages through participating in a national registry” and discussing the implications of the current registry function, the SVS recommends that the current NCD consideration (or a subsequent NCD) be created to consider a requirement that national society registries serve as the CAS outcomes reporting mechanism, with simultaneous discontinuation of the current CMS CD-based data submission system. This would assure collection of CAS data with sufficient pre- and post-procedural variables to allow scientifically valid and extremely valuable risk-adjusted outcomes analysis. While we know of two functioning specialty-society registries, (VR and NCDR-CARE), our intent is not to exclude other potential entries. The important concept is that new CAS registries should include detailed demographic and clinical variables equivalent to the extant registries.

A second requested change in the NCD is that reporting requirements be extended beyond the initial hospitalization to at least 30 days and potentially to 12 months since CAS procedures have event rates documented to occur after hospital discharge. The graph below indicates the significant incidence of post-CAS adverse event that occurred after hospital discharge. The data in this graph represent outcomes in 1450 consecutive CAS patients for whom post-discharge data was entered in VR. Without a post-discharge reporting requirement, the challenge to acquire crucially important data beyond the initial hospitalization is significant.



SVS and other specialty society CAS registries would analyze and submit the collected data to CMS. SVS suggests that CAS-approved facilities would still be required to

submit an affidavit to CMS verifying complete and accurate entry of all data on all CAS patients. This would serve to guarantee comprehensive reporting.

SVS greatly appreciates the extensive effort extended by the CAG in developing this important coverage policy and in supporting the numerous re-considerations of this decision. Thank you for your time and consideration.

Sincerely Yours,

Gregorio Sicard, M.D.
Chair, SVS Outcomes Committee

Robert M. Zwolak, M.D., Ph.D.
Chair, SVS Health Policy Committee

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